EXHIBIT X

SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF KERN
CASE NO. S-1500-CV 279123 LHB

COLEEN M. PERRY, PLAINTIFF

vs.

HUNG T. LUU, M.D., JOHNSON & JOHNSON, a New Jersey Corporation; ETHICON, INC., a New Jersey Corporation; and DOES 1-60, DEFENDANTS

The deposition of SCOTT A. GUELCHER, Ph.D., called by the Defendants for examination, taken before Michelle E. Kerr, RPR, a Notary Public in and for the Commonwealth of Kentucky, Daviess County, at 1719 West End Avenue, Nashville, Tennessee, on December 18, 2014, commencing at 9:40 a.m.

APPEARANCES

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EXHIBITS

SCOTT A. GUELCHER, Ph.D.,
HAVING FIRST BEEN DULY SWORN TO TELL THE TRUTH, THE WHOLE TRUTH, AND NOTHING BUT THE TRUTH, TESTIFIED AS FOLLOWS:

DIRECT EXAMINATION

BY MR. SNELL:

Q State your name for the record, sir.
A Scott Guelcher.
Q What profession are you in, Dr. Guelcher?
A I'm an Associate Professor of Chemical Engineering at Vanderbilt University.
Q You understand we're here today to take your deposition in the Coleen Perry case, which is currently pending in California?
A I do.
Q And you're here today to give your opinions and the bases for those opinions, correct?
A Yes.
Q When were you first contacted to serve as an expert in the Perry case?
A I believe it was September, September '14.
Q So in September of 2014, you were contacted to be an expert in the Perry case?
A That's what I remember.
Q Who were you contacted by?

A By plaintiff's counsel, Jeff Kuntz and Tom Cartmell.
Q And what did you understand your assignment to be in relation to the Coleen Perry case?
A Assignment, I'm not sure what you mean by that.
Q What did you understand your purpose was to be as an expert involved in the Perry case?
A Well, I was testifying about defects in the Abbrevo mesh.
Q Did you say effects?
A Defects in the Abbrevo mesh product.
Q You have given other deposition and trial testimony in mesh litigation, correct?
A Yes, I have.
Q You testified in the Huskey case that involved Ethicon's TVT-O product, correct?
A I did.
Q You were deposed and gave trial in West Virginia, correct?
A That's correct.
Q And at the time that you gave that testimony, it was under oath as well, correct?
A That's correct.
Q And did you tell the truth in that testimony?

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A Yes.
Q How many hours have you spent on the Perry case?
A I'm not sure. I haven't billed any invoices for time yet, so I don't know the total number of hours.
Q Can you give me your best estimate?
A I don't know. Maybe 20. But when I submit my invoices, that will be the more reliable number. I haven't added it up yet.
Q Well, do you have the invoices on your calendar?
A No.
Q In the Huskey case, you testified that you submitted your invoices to Dr. Dunn in connection with that matter. Do you recall giving that testimony?
A That's correct.
Q Are you submitting your invoices to Dr. Dunn in the Perry case?
A I'm not sure yet how that will be. I'll be billing -- my plan is -- it's not resolved yet, whether I will independently or through Dr. Dunn's company.
Q How do you track your time that you spend in

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the Perry case?
A I have some paper records, but it's not -- nothing is official. I've not been releasing -- in the past, all the invoices have been submitted through Dr. Dunn's company. Nothing is official until I submit the invoices. I don't have the invoices right now.
Q Well, in the Huskey case, you testified under oath that you submitted monthly invoices to Dr. Dunn, which included the time spent, the time of day spent and a brief description of your activities. Do you recall giving that testimony?
A I do.
Q And at what point in time has that changed?
A Very recently. In the past maybe month or two.
Q When was the last time you sent an invoice to Dr. Dunn with regard to your work as an expert in mesh litigation?
A I don't remember. Maybe a month or two ago. I don't remember the date.
Q As I understand it, Dr. Dunn received a cut from the amount billed for your work in the

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Huskey case. Do you recall giving that testimony?
MR. KUNTZ: Objection.
A I'm not sure what you mean by a cut.
BY MR. SNELL:
Q In the Huskey case, as I recall it, you received $200 per hour for review and work, correct?
A I don't believe that's -- well, it was 200 or 210. He raised the rates. Okay. It was 200 or 210. The rates have been changed, and I don't remember if it was before or after Huskey. It may have been 200. It may have been 210. I can't remember.
Q And Dr. Dunn billed $275 an hour for your review time, correct?
A If I bill 200, then Dr. Dunn would have billed 275.
Q And is it your testimony that that arrangement has changed within the last one to two months?
A Yes. I have not submitted any invoices for this case, but the plan for moving forward is for me to submit invoices independent of Dr. Dunn's company.

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Q Do you have your own company that you will be submitting invoices under?
A I do.
Q What's the name of that company?
A Guelcher Consulting, LLC.
Q In the Huskey matter, you testified that you kept a calendar and a recording of your time spent and the days that you worked as an expert. Do you recall giving that testimony?
A I do.
Q Have you done the same thing here?
A I have not. Not in the same way.
Q Why not?
A I just changed it. I have a right to change the way I keep the time.
Q So what materials or documents do you have that would reflect the time you've spent up until the time of this deposition for the Perry case?
A I don't have them yet because I haven't submitted the invoices. That's what I said.
Q I'm not asking about invoices.
I'm asking what other materials or documents -- what would you look to to draft an invoice so that you would know the

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accurate amount of hours for your billing that you would submit?
A I have some paper at home.
Q What paper at home?
A Well, I have a piece of paper that has hours written on it, but I haven't added everything up yet because I haven't submitted the invoice.
Q Is this a piece of paper in a notebook or --
A No, it's just a note.
Q Do you have a copy of that that you can give to counsel?
A No, I don't, because we haven't been doing that. We've been providing invoices, and Dr. Dunn was providing invoices, and I just don't have an invoice yet that I've sent in. Until it's finalized, I don't -- I've not been submitting records of time until there is a final invoice.
MR. SNELL: Well, I'm going to make a request that you get a copy of that to counsel, and we'll attach it to the deposition.
MR. KUNTZ: We'll get you a copy.

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A I can send an invoice after today and that will make it official. Is that okay?
BY MR. SNELL:
Q Well, that's fine. But I'd like to know what it is because I will have questions about that potentially.
A What is? I don't understand. You said you'd like to know what it is if I send you an invoice. You know what it is. It's an invoice that says my hours and what I did, so I'm not sure what you're looking for.
Q Well, right now you currently have -- you testified you have a document that has your hours and the time you spent. That's the document I would like. If you draft an invoice, I would like that as well.
A Okay.
Q When did you form Guelcher Consulting, LLC?
A It's been very recent. In the past few weeks maybe.
Q What happened between you and Dr. Dunn that led you to believe that you should go out independent of Dr. Dunn?
A Nothing happened with Dr. Dunn. I'm not sure what you're asking me.

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Q For over a year, you submitted invoices through Dr. Dunn and his company, correct?
A That's correct.
Q Is it your testimony that there was nothing that made you decide to go out and become independent of Dr. Dunn?
A Well, that's not what you asked me the first time. You ask me what happened, implying that something disruptive happened in our working relationship, which nothing happened. It's just a decision to do this independently.
Q How much are you billing now for your work --
A The same rate.
Q Let me finish my question.
A Sure.
Q How much are you billing for your time as an expert in the Perry case for review of materials?
A The same rates as Dr. Dunn.
Q Can you tell me how much per hour?
A Dr. Dunn raised his rates from 275 to 285 for report writing, reviewing of documents, etc. I will be charging that rate. For testimony, I just can't remember the number right now.

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I think it's maybe 385 is a number for testimony, but that would be on the invoice. I can't remember the number right now.
Q So it's your intention to bill $285 per hour for reviewing materials and report writing and things like that?
A That's what Dr. Dunn was billing. And since I'm doing the same activities, I thought it reasonable to bill the same rate.
Q Dr. Dunn is not an expert in this case. You're aware of that, correct?
A My understanding is that Dr. Dunn has not been produced as an expert witness for Plaintiffs.
Q All right. So for you -- I just want to get a clean answer without injecting Dr. Dunn into this Q and A. The rates that you, Dr. Guelcher, are charging for report writing and review of documents for this matter in the Perry case will be $285 per hour; is that correct?
A That's correct.
Q The rate that you will charge for testimony, as best as you can figure at this point in time, is $385 per hour?

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A That's correct.
Q Will you have a different rate for trial testimony if you are called to testify at trial?
A I don't believe so. I intend to use the same rates that were being billed in the past, and there was no difference between trial and deposition testimony. Those numbers were the same. So whatever those numbers are, it will be the same. There won't be a difference.
Q You understand that this trial will be in California?
A Yes.
Q And you're agreeable to traveling to California for trial?
A Yes.
Q Your expenses of traveling to California, would you bill for those?
A That's what Dr. Dunn has done in the past, and I would continue that practice.
Q So if you come to trial in California, you will bill for your expenses, such as air fare, and hotel room, and meals, correct?
A Yes, that's correct.
Q Have you ever met Mrs. Perry?

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A I have not.
Q Have you spoken to Mrs. Perry?
A I have not.
Q Have you ever spoken to any of Mrs. Perry's family or friends?
A No.
Q Have you ever spoken with any of Mrs. Perry's doctors?
A No.
Q Okay. Have you spoken with any other experts about the Perry case?
A Any other experts defined as --
Q Defined as -- let me ask you this. Besides yourself, who do you understand to be the other experts besides yourself in the Perry case?
A I don't know who the other experts are that they are calling. I haven't spoken with them.
Q So you have not spoken with a Dr. Rosenzweig about the Perry case?
A I have not.
Q Have you ever spoken with Dr. Rosenzweig?
A I have not.
Q Dr. Michael Thomas Margolis from California,

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have you ever spoken to him?
A No.
Q Okay. Dr. Donald Marks, he is another expert --
A I have not.
Q You have not spoken with him?
A No.
Q Have you reviewed any expert reports or expert declarations in the Perry case?
A Yes.
MR. KUNTZ: Aside from this own?
MR. SNELL: Yes, of course.
BY MR. SNELL:
Q Let me just take that off the table and reformulate.
Setting aside your expert declaration listed opinions, have you reviewed any other experts' declarations or listed opinions?
A Declarations, no, I don't believe so.
Q Okay. For your opinions in this case, you're not relying on the declarations or reports of any other experts, correct?
A No, I'm not relying on any other declarations.
Q You're not relying on any other experts'

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opinions, correct?
A Yes.
Q Do you know if any independent medical examinations have been done on Mrs. Perry?
A I'm not aware of any of those outcomes of those medical examinations. I've not reviewed that.
Q So you haven't reviewed any of the IME outcomes or reports in this Perry case, correct?
A No.
Q I'm not correct?
A I have not reviewed, yeah. I'm sorry.
Q Okay. And you're not relying on the outcomes of any IME reports; is that correct?
A Yes, that's correct.
Q When you do issue your invoices or invoice for the Perry case, will the check be made payable to Guelcher Consulting, LLC, or to you personally?
A It will be made to the LLC. I'm the sole owner of the LLC, so it will be made to the LLC.
Q Is Guelcher Consulting, LLC, a Tennessee corporation?

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A Yes. It's been registered with the secretary of state.
Q As I understand it from your testimony at Huskey and other matters, you believe your expertise is in the field of biomaterials design?
A That's one way of saying it. I have expertise in biomaterials science and engineering. Another way you could say it is that my work involves design of materials for use as bone grafts or skin grafts, design of biomaterials as diagnostics for studying cancer metastasis.
Q You have a Ph.D., correct?
A Yes.
Q Any higher education than that?
A I did a postdoctoral research training at Carnegie Mellon in biomedical engineering.
Q But that was not something for which a degree was earned; is that correct?
A It's not a degree, but it's postdoctoral training. It counts as training.
Q You're not a medical doctor, correct?
A No, I'm not a medical doctor.
Q You're not a pathologist?

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A I'm not a pathologist.
Q You don't treat any patients, correct?
A I don't treat patients.
Q You're not a toxicologist, correct?
A I'm not a toxicologist.
Q What is the difference between your expertise and Dr. Dunn's expertise?
A So Dr. Dunn and I have overlapping expertise in polymer science and engineering. My expertise is differentiated from Dr. Dunn's in biomaterials, preclinical testing of biomaterials, evaluation of biomaterials using in vitro and in vivo models. Those would be some examples of how my expertise is differentiated from Dr. Dunn's.
Q Is Dr. Dunn more of a polymer chemist than you are?
A I would not state it this way. I've had extensive experience in polymer chemistry, science and engineering. I've worked for several companies in the area of polymers. My postdoctoral training was in polymers for bone scaffolds. And for the past ten years at Vanderbilt, I've been working on polymers and I taught -- and I developed and taught a

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course on polymer science and engineering at Vanderbilt.
Q In prior cases, as I understand it, and have read your testimony, Dr. Dunn, if testing was done, he would have been the one to perform the testing on meshes?
A That's correct, Dr. Dunn did the testing.
Q Is there a certain reason for that?
A The reason relates to the nature of our employments at Vanderbilt. Dr. Dunn is a professor of the practice. I'm a tenured associate professor with a federally-funded research program. And so we have different appointments, that's the reason.
Q I don't understand that.
Can only professors do the type of testing that he performed in the prior cases?
A I'm qualified to do the testing. It's that I have graduate students working in my laboratory on federal research grants. Dr. Dunn has a company with employees. It's simpler for him to do the testing than for me from an administrative perspective. So that doesn't have anything to do with qualifications or ability. It's more because

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of these practical reasons.
Q So you have graduate students working under you who are being subsidized, whose work is being subsidized by federal funding; is that correct?
A I wouldn't say it's being subsidized. The work is being funded by federal funding, and in some cases, by corporate funding. Their stipends are paid either from fellowships or from the grants, not from the consulting.
Q Okay. Well, what about the fact of graduate students working under you who are supported by federal funding, what affect does that have on why Dr. Dunn did the testing and you didn't?
A Well, to have graduate students working on that sort of testing would require a disclosure to the university, so I haven't had them involved. I've disclosed the consulting activity to the university required by the policy, but to have graduate students involved would require more, and I just haven't done that at this time.
Q What type of disclosure did you make to the university with regard to your goal as an

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expert witness?
A Every year we are required to file a disclosure report that would include -- because I have NIH grants, the NIH requires us to disclose travel funded by third parties. I'm required to disclose relationships with companies that I have had grants from companies in the past, consulting relationships with companies. These activities are disclosed.
In the past what I've disclosed is that I was a consultant working for Polymer and Chemical Technologies.
Q So your disclosure stated that you worked as a consultant in polymer and --
A For Polymer and Chemical Technologies. That's Dr. Dunn's company. So last year's disclosure, that's what I have filed. I have to update it this year again.
Q Did you identify in your disclosure that you were serving as an expert on behalf of plaintiffs in the transvaginal mesh litigation?
A We're not required to disclose the activity, only the fact that we're consulting.

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Q So you did not disclose that you were consulting with plaintiffs' attorneys in transvaginal mesh litigation?
A I don't remember what I disclosed right now, the exact details. I disclosed that I had a consulting relationship. I don't remember the detail of what I exactly disclosed. I would have to look at it again.
Q Now, that you're billing your services directly through your own corporation, are you going to disclose that you are consulting and serving as an expert to plaintiffs in transvaginal mesh litigation?
A When I submit the invoices, I will update the disclosure, but that hasn't been finalized yet. When I submit the invoices, I will update the disclosure.
Q Where does this disclosure get submitted to within Vanderbilt?
A At the dean's office, dean of engineering.
Q If you do any testing of meshes in your role as a plaintiff's expert, and you utilize any of Vanderbilt's equipment, personnel, or any other assets owned by Vanderbilt, do you have to give prior notice of that to Vanderbilt?

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A That's a complex question. It depends on what's being used and the specific faculty member. It would have to be discussed with the university. I don't know the answer to that. There is not a fixed answer to that question.
Q If you have one of your graduate students who is supported by federal funding analyze meshes from the mesh litigation, would you have to disclose that to anyone?
A I would discuss that with the dean's office. But Dr. Dunn's company did the testing, so --
Q Where is Dr. Dunn's company located at?
A At his residence in Nashville.
Q He has employees working out of his home in Nashville?
A I can't speak to those details about Dr. Dunn's company. I don't know how he operates his company other than his business relationship with me.
Q Do you know if Dr. Dunn utilized any of the graduate students at Vanderbilt in any analyses pertaining to transvaginal mesh?
A Not to my knowledge.
Q Do you know if Dr. Dunn utilized any

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Vanderbilt personnel besides yourself in any analyses or investigation pertaining to transvaginal mesh?
A Again, Dr. Dunn would have to speak to that. I don't know.
Q Who is your immediate supervisor currently?
A My department chair, Kane Jennings.
Q Could you spell that?
A K-A-N-E Jennings.
Q And that's within the department of what?
A Chemical and biomolecular engineering.
Q So you work within the Department of Chemical and Biomolecular Engineering at Vanderbilt?
A That is correct.
Q Is that a particular school at Vanderbilt?
A That department is within the school of engineering.
Q Besides Dr. Dunn, who, if anyone else at Vanderbilt is aware that you are serving as an expert for plaintiffs in the transvaginal mesh litigation?
A Professor Ken Debelak, D-E-B-E-L-A-K. He's an Associate Professor of Chemical and Biomolecular Engineering at Vanderbilt. Dr. Dunn retained him through his company as

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an expert in prior litigation over a year ago. I believe Dr. Debelak was deposed in this first case, but not since.
Q Have you had anyone at Vanderbilt perform any activity on your behalf with regard to anything you've done in the transvaginal mesh litigation as an expert?
A So I have a graduate student who was doing oxidative degradation testing through her dissertation project, and she provided -- well, I asked my graduate students to write standard operating procedures for everything we do. I review and discuss those procedures with them and approve them, and she gave that protocol to Professor Dunn.
Q What's the name of this graduate student?
A Anne Talley, T-A-L-L-E-Y.
Q Let me see if I understand this. So you asked all of your graduate students to write SOP's?
A So for anything that we do in the laboratory, for any polymer that we make, for any analysis that we run, such as oxidative degradation testing, we review the literature and prepare a standard operating procedure or

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an SOP for the procedure, and I believe that's part of student training. These are the types of activities they will do in the industry, so I ask my students to write these types of documents.
Q What did you ask Anne Talley to do specifically that pertained to your work as an expert in the transvaginal mesh litigation?
A I didn't ask her -- I asked her to write the SOP for the medium, preparing the medium. And then Dr. Dunn asked her for that SOP is my understanding.
Q Why did you ask Ms. Talley to write the SOP for the preparation of the medium?
A Well, she was the one that was working in this area on her research project, so she had the most knowledge about it.
Q When you say medium, what medium are you referencing?
A The medium that was used in the in vitro testing with the mesh.
Q What was that medium?
A It's a solution of 20 percent cobalt chloride -- I'm sorry. Strike that. It was a

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solution of 20 percent hydrogen peroxide with cobalt chloride, and I don't remember the exact amount. That's the solution.
Q And this solution is used for the in vitro testing of mesh?
A This solution was first developed by Dr. Jim Anderson in 1993. It was first published -- his group published a number of papers on it. I published two papers with it. It's used to assess the degradation of biomaterials under oxidative conditions that are similar to those in the human body, more specifically, that are similar to those under conditions where there are adherent inflammatory cells in the biomaterial, the foreign body reaction, I should say, the effects of the foreign body reaction on the stability of the biomaterial.
It's a very general well-known established test that's been cited dozens of times.
Q So did Ms. Talley or any of your other graduate students do any in vitro testing on the mesh?
A No. As I said before, that testing was done

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by Dr. Dunn's company.
Q Was the testing done by Dr. Dunn's company before or after Ms. Talley's SOP was given to Dr. Dunn?
A I believe it was after, because they used that SOP to prepare the solution. These activities were done by Dr. Dunn, but I don't know who in his company did what. I just know that my lab through Anne provided them with a solution with a -- strike that -- with an SOP for preparing the solution, and then they did the testing.
Q Did Ms. Talley know that she was writing an SOP that would be given to plaintiffs' experts in the transvaginal mesh litigation for utilization in certain testing?
A She did not prepare the SOP for plaintiffs. She prepared the SOP for use in my laboratory. She was aware of the mesh litigation, but she was not -- she did not write it for this. It's an SOP for my laboratory. It falls within the scope of her activities on her funded research project.
MR. SNELL: Move to strike.
BY MR. SNELL:

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Q Did Ms. Talley know that she was preparing an SOP that would be given to a plaintiff's expert for use in transvaginal mesh litigation?
A The way you asked that question, no, I don't believe so. It was written for my laboratory. She did not write it for the testing. It's an SOP that was in my laboratory.
Q How long did it take Ms. Talley to write this SOP?
A I don't know.
Q Did you assign Ms. Talley to write this particular SOP regarding this testing?
A I believe so. I asked her to write the SOP for the procedure in general to use in our lab. We use it for other projects as well.
Q You were aware when you asked Ms. Talley to write the SOP regarding the testing, that it would be used by Dr. Dunn in his role as an expert for plaintiffs in the mesh litigation?
A I was aware of that.
Q Did Dr. Dunn give Ms. Talley any money or renumeration for writing this SOP that he used in his role as an expert in the mesh

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litigation?
A He wouldn't give her renumeration because it was written within the course of her work at Vanderbilt and her project.
Q So the answer is, no, he didn't give her any money?
A No.
Q And did you give Ms. Talley any money or renumeration for writing the SOP that you were aware of that would be used in testing meshes in transvaginal litigation?
A I didn't give her money because it was written for her research project for her work at Vanderbilt.
Q So the answer is no, you didn't give her any money, correct?
A No, but for that reason. It wasn't written for the mesh litigation.
Q Other than Ms. Anne Talley, have you involved any of your other graduate students in any testing or analyses pertaining to your work as an expert in the transvaginal mesh litigation?
A No.
Q How long ago was it that Ms. Talley wrote

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this SOP?
A I don't remember. I don't know when exactly she wrote it or when it was revised or finalized. I don't remember.
Q Well, was it this year or last year?
A I don't know.
Q When did Dr. Dunn do this testing that he utilized Ms. Talley's SOP that she wrote while as a graduate student for you?
A It was done in September.
Q Of 2014?
A Yeah.
Q So, certainly, Ms. Talley would have been working on this SOP during the calendar year of 2014, correct?
A She would have been working on it. Typically, these are documents that we write and we revise, so I have had students write SOP's, and then other students come back and revise them. That's how we do it. We revise them based on new papers that have been published, new information, so I don't know the history of the document. I can't remember that.
Q Is Ms. Talley currently a graduate student at

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Vanderbilt?
A Yes.
Q If you had done any of the types of testing that Dr. Dunn has performed in his role as an expert in the transvaginal mesh litigation on the mesh, what type of paperwork or disclosures would you have had to give to Vanderbilt?
A I don't know. It's difficult to answer these questions. We tend to address them when -- I just -- as I said earlier, I have not been doing testing of materials for litigation at Vanderbilt, so I don't know what I would have to do. So far I've disclosed the consulting activity. I may very will make additional disclosures as we move along and the situation changes, but it's a very fluid situation.
We disclose these types of things as they arise. So it's difficult to say without actually seeing the situation.
Q Does Vanderbilt require you to disclose any relationships upon which you receive outside monies?
A I already answered this. We're required to

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disclose consulting relationships. When I submit a grant application, I'm required to disclose whether I have a significant financial interest. The NIH changed the rules in 2012. I disclose whether there is a significant financial interest, and then the dean's office works with me to figure out if there is a conflict, and if there is, how do we manage it.

So there is no fixed set procedure. It's very much handled on a case-by-case basis. And disclosures are continuously updated as new information becomes available.

Q How is significant financial interest defined?

A The NIH defines a significant financial interest as $5,000 a year. That's one way to define it. Another is equity. Strike that. The NIH defines it as $5,000 or greater. Financial interest, that could be cash. That could be equity. That could be any form of compensation, but the threshold is $5,000.

Q Have all monies you receive in your role as an expert in the transvaginal mesh litigation for the calendar year 2014 been paid to you

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through Dr. Dunn's company?

A The money I have received has all been received through Dr. Dunn's company, that's right, yes. The money I received, yes.

Q Does anyone at Vanderbilt know the scope of Dr. Dunn's company?

A I can't speak to Dr. Dunn's company. I don't know the details of his arrangement with the university. I just don't. He has a different type of appointment than I have. He doesn't do federally-funded research. That's what I know. I don't know the details of his arrangement with Vanderbilt.

Q Is Dr. Dunn in a position of authority over you at Vanderbilt?

A No.

Q If Dr. Dunn wanted to do federally-funded research, would he be able to in light of his activities and the amount of money his company bills for expert work in the transvaginal mesh litigation?

A I can't speak to that. I don't know how much his company bills or makes. I don't know that information.

Q Have you investigated what affect your

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independent role now as an expert and billing as an expert will have on your ability to work or run a lab that has federally-funded research?

A Yes, I have.

Q And what affect, if any, have you learned about that?

A I'm contemplating updating my disclosure. And -- well, I will leave it at that.

Q Have you had any discussions with anyone at Vanderbilt about ways you could work around the ramifications that the receipt of federal funding has on your role as an expert?

MR. KUNTZ: Objection.

A I don't like this word work around. That's not what we do. We identify conflicts. We disclose information to the dean's office. We work with the dean's office to identify conflicts. If conflicts are identified, we work with the dean's office and the general counsel's office to identify and manage a plan, which is then approved -- approved by the conflict of interest committee.

I've been through this process multiple times. I've had management plans. I've been

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disclosing conflicts to Vanderbilt since I started there. There is a very standard and routine process. Faculty are allowed and encouraged to participate in activities outside of Vanderbilt. I do this in the course of my research with licensing, start-up companies. This is routine.

There is a process and a procedure. And we're not working around anything. We're trying to find a way to work within the framework of the federal regulations and university policy. It's very standard for universities.

BY MR. SNELL:

Q Have you told Vanderbilt how much money you have earned as an expert in the transvaginal mesh litigation?

A You have asked me this before. And I said we are not required in the course of our work to disclose that. If I believe that I see a conflict between my research and the consulting, then I will disclose that and the university will -- we will have those discussions, but we are not required to disclose this information for consulting

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work.
Q So the answer to my question is, no, you have not disclosed that to Vanderbilt, correct?
A I'm not required -- strike that.
Q My question is simple. Have you disclosed to Vanderbilt --
A And I believe I have answered your question.
Q I think you are telling me about what you're required to do.
I'm asking you, have you, Dr. Guelcher, disclosed to Vanderbilt the monies, the amount of monies you have earned as a plaintiff's expert in transvaginal mesh litigation?
MR. KUNTZ: Object. Answer it.
BY MR. SNELL:
Q It's a yes or no answer.
A No, I've not disclosed, but I'm not --
Q Have you informed your dean of your current intention to bill as an independent consultant to attorneys in the transvaginal mesh litigation?
A Why would I inform the dean of this? I've not informed the dean. I have to inform the dean when I believe there is a conflict. And

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if and when I make that assessment, I will update my disclosure. But according to Vanderbilt policy, we're not required to do those things.
Q Well, if you spent approximately 20 hours at $285 an hour thus far, that is over $5,000. Are you telling me that if you have a greater than $5,000 interest in your role as an independent billing consultant to transvaginal mesh litigation, you do not need to tell that to the dean?
MR. KUNTZ: Objection.
A No, you are misinterpreting and misunderstanding what I have said. The question is, whether the proposed research, when I submit a grant application, I submit an application to the NIH for federal funding. I have to answer the question, do you have a significant financial interest in the outcome of this federally-funded project.
Significant financial interest is defined as more than $5,000. But at this point in time and in the past there -- at this time, there is no overlap between the consulting work and the federally-funded research. So

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if and when I submit a grant application, that would create the conflict, but that's tied to INH funding. That's not -- why I'm not required to disclose it unless there is a conflict of the federally-funded research project.
Q Have you performed any testing on Ms. Perry's mesh?
A I have not.
Q Have you looked at Ms. Perry's mesh under a scanning electron microscope?
A I have not.
Q What are all of the different tests, methods that one can do to try to determine whether there is degradation of polypropylene?
A So degradation of polypropylene could be assessed by SEM imaging. That's typically how we assess it.
Q FTIR --
A FTIR -- I'm sorry.
Q FTIR is a way that one can go about trying to assess whether there is degradation of polypropylene, correct?
A No, that's not why we use FTIR. We use FTIR to assess for oxidation, chemical changes in

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the polypropylene. That can be assessed by the FTIR.
Q And when you look for oxidation via FTIR, what you are looking for is to see if there is a potential that would lead to degradation; is that correct?
A No. We are looking at oxidation to answer the specific question of is the surface oxidizing, is it chemically changing. And we can see that by peaks in the FTIR spectra that are not there in the normal polypropylene, but do appear for oxidized polypropylene.
Q Now, as I understand it, Dr. Dunn, in prior work did FTIR in connection with assessing the question of is there degradation of polypropylene?
A And why is that -- I don't know what you're referring to.
Q I recall in your Huskey testimony, in your deposition, you testified that all of the testing done was done by Dr. Dunn. And I believe you identified FTIR, XPS, and I don't know if there were others.
A I don't remember the testing that Dr. Dunn

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did for the Huskey trial. I do believe we did FTIR. I don't remember the others, but oxidation and degradation are related, but they're -- in terms of -- and there may be times that people use the word degradation to consider all of these effects, but I'm speaking specifically about oxidation as a chemical process, and degradation as a physical one, and they're assessed by different techniques.

And I don't remember all of the testing that Dr. Dunn did for the Huskey trial. I don't remember that.

Q So if one does FTIR testing and sees that the surface is oxidized, that does not necessarily mean that the material is degraded, correct?

A There are different tests to assess -- they could be degraded, but we would assess degradation using a different technique than FTIR. FTIR, as I said, is for chemical oxidation, which is a chemical change. There may be degradation, but we would confirm that with a technique such as SEM.

Q So if a scientist has a positive FTIR finding

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for oxidation on the surface, he would then need to confirm that with SEM in order to reasonably say with scientific certainty that there was degradation?

MR. KUNTZ: Objection.

A I would say that the literature teaches us that these processes are related, oxidation. Chemical oxidation leads to physical degradation. And so if I see evidence of oxidation, I would expect to see physical degradation in time. To visibly see that physical degradation, I would do the technique such as SEM.

But if I see oxidation, I would certainly expect based on published literature findings that there would be degradation in time to some extent.

BY MR. SNELL:

Q Well, if you see chemical oxidation, it is not a guarantee that physical degradation has taken place, correct?

MR. KUNTZ: Objection.

A I think I just answered that. It's a strong indicator that there is also physical degradation.

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BY MR. SNELL:

Q The fact that's it's a strong indicator, though, that in and of itself means that there is some possibility that you will not see physical degradation, and there is a possibility as well that you will see it, physical degradation, if you look at SEM, correct?

MR. KUNTZ: Objection.

A Again, the literature tells us that you would expect degradation. Is it -- unless you actually see it, you can't prove -- you can't guarantee that it's there, but you would certainly expect it. It's within a reasonable degree of scientific certainty to expect that you would have degradation in time if that surface is being oxidized.

There are numerous papers that teach about this, about polymers in general, polymers that are susceptible to oxidative attack showed signs of physical degradation. This was all worked out a number of years ago.

MR. SNELL: Move to strike.

BY MR. SNELL:

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Q My question is this. It's straight forward. The fact that you see chemical oxidation, that does not mean that you would also see under SEM analysis physical degradation if you were to look at that particular time; is that correct?

MR. KUNTZ: Objection. Asked and answered. Calls for speculation, and is an incomplete hypothetical. But go ahead.

A This is a speculative question. What I'm saying is, if there is oxidative changes, the body of literature teaches within a reasonable degree of scientific certainty that there will be at some time physical degradation. That's what the literature is teaching us.

BY MR. SNELL:

Q You keep saying at some time there will be physical degradation. At what time will there be physical degradation?

A As I've said in my previous testimony, it's unpredictable. And that's a problem for the design of the device, because it's subject to changes that can happen that you can't predict the timing of these changes and what

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the implications will be.
Q Do you have an opinion as to what is the earliest point in time where there can be physical degradation of Ethicon's Prolene polypropylene used in TVT Abbrevo?
A Again, that's a speculative question. I believe that upon implantation, the device will be colonized by adherent inflammatory cells. This is well-known in the literature, the foreign body reaction. Those cells will secrete species that oxidize it. The timing of all these events can depend on a number of factors, the nature of the inflammatory response where it's implanted, the mechanical stresses in the environment, whether there is a bacterial infection.
The timing can be highly variable. It can happen early or it can happen late. The point is that it's unpredictable. That's what I've been saying.
Q Well, I would like to know what does the literature teach you about the earliest point in time when you can say there is physical degradation of the Prolene polypropylene mesh?

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I don't want to rehash everything you talked about in Huskey. I know you talked about what was seen in two years and I believe five or seven years in a dog study and things like that. So with all of those principles that you've already testified about, let me just back up and re-ask it.
A Okay.
MR. KUNTZ: Objection.
BY MR. SNELL:
Q What is the earliest point in time that you can say that there is physical degradation of the Prolene polypropylene mesh?
A I just can't answer that question. There are too many factors that can influence it. To say -- again, it's too speculative. It depends on many factors in addition to the chemical oxidation.
Q Based on all of the literature that you saw, what was the earliest time reported that there was physical degradation of the Prolene polypropylene mesh?
A For Prolene polypropylene, I can say from the Clave paper and the explants that were studied in Clave, he recorded degradation in

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time periods of three months and later. That's what Clave reported.
Q And you have a list of materials here today. Where in Clave does it say that --
A I would have to see the paper. I know that in Clave, it says that -- he notes that explants -- I would have to see it to give a precise answer. The number I remember is three months.
(Deposition Exhibit No. 1 was marked for identification.)
BY MR. SNELL:
Q Doctor, I've handed you Exhibit No. 1. Is that the Clave paper you were referring to, sir?
A That is correct.
Q So can you show me where in Clave it states that physical degradation occurred in the Prolene polypropylene mesh at a certain time period?
A I'm looking for that. So on Page 264 of Clave, it states degradation was observed only in samples implanted for at least three months.
Q That is a general statement about the overall

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cohort of explants, correct?
A That's my understanding.
Q That statement is not necessarily particular to a Prolene polypropylene mesh implant, correct?
A There could have been Prolene implants in this study. That statement doesn't specify whether that applies to Prolene or not.
Q So my question is, can you point to any literature which informs you of the earliest time which the Prolene polypropylene mesh physically degrades?
MR. KUNTZ: Objection.
A I don't know of this -- you mean in vivo of patients?
BY MR. SNELL:
Q Yes, sir.
A I don't know of a study that has specifically reported that.
Q In the dog study -- and you're still relying on the dog study as well with the Prolene sutures?
A The dog study, it's in my reliance materials, so it's part of the documents I have reviewed.

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Q At what point in time was physical degradation observed in that study?
A I can't remember. I would have to look at the document.
Q Okay. At a break, I would like for you to look at that document. And I will have the same question for the vascular graft Prolene suture study, what is the earliest point in that study if at any point in time it showed physical degradation?
A Again, I would have to look at it. I don't remember that level of detail.
Q Am I correct that although Clave reports there were 100 explanted samples, a smaller number were actually analyzed?
A What do you mean analyzed? I'm not sure what you mean.
Q Let me ask you, how many explants were analyzed in the Clave study?
A I would have to look at it. There were 100 explants. I'm still not sure what you're asking, though. I mean, there were 100 explants.
Q How many of those 100 explants were actually analyzed?

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A Well, I think it depends on the method, so -- they did a chemical analysis on 32 explants. It doesn't necessarily say in the methods.
Q Why did Clave do less than one-third of the overall sample size for chemical analysis?
A I don't know. I would have to look at this to --
Q By only analyzing 32 out of 100 explants for a chemical analysis, what limitations does that place upon the interpretation one can draw from the Clave paper?
A Well, what I believe Clave is saying is consistent with my opinions, that these events can happen and can lead to problems and complications. He's not saying it happens all the time in every mesh at this particular time.
He is saying that these meshes change, which is consistent, which is my opinion in this case, that the meshes change, and that introduces an extra level of risk because these changes make the meshes -- make their behavior unpredictable. That is what he is saying.
MR. SNELL: Move to strike.

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BY MR. SNELL:
Q My question was not what is he saying. My question was to you, what limitations does that place upon what one can draw from Clave due to the fact that only 32 out of 100 explants were submitted for chemical testing?
A I don't see how it limits the finding that he sees changes. That's what he is reporting, whether he sees it in 32 or 50, whether he looked at 32 or 100. I mean, you may be implying that he was cherry-picking data, but I have no reason to believe that. This is a peer-reviewed journal.
I mean, he studied what he could study, but it doesn't limit the finding that these changes happened. Whether he did 32 or 100, he still saw changes. So I don't understand how that limits that finding.
Q Well, he had 100 explants, and he only subjected 32 to chemical analysis. We can agree to that, right?
A That's what he states. But beyond that, I don't --
Q And you don't know the methodology by which he selected the particular 32 for chemical

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analysis, correct?
A Well, let me read it. I need to read this, because I'm not quite following where you are going with this.
Okay. So he says -- I mean, he explains himself. The samples were divided into four groups. Because of the small sample size and physical condition of the explanted materials, extensive and complete chemical analysis was difficult, which I think most would agree is true. And he has several groups listed here, four groups.
One of the fourth group is a control with pristine implants, which he has a number of pristine implants listed. So he grouped one as degraded polypropylene that he analyzed by SEM.
Group two is a group of nondegraded explants, which again looks like polypropylene mesh. And then the fourth group of PET explants. That's what he says he did. And he says it was difficult. He probably didn't have much material to work with, but these are explants. This isn't a clinical trial. These are explants, so that

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is what he had to work with.
Q But do you know then the methodology by which he determined the cut point for whether it was too difficult or not to do SEM analysis?
A He doesn't provide more detail, but this is what I understand that he did.
Q So we have no way of knowing what chemical analysis would have shown for those 68 explants that were not subjected to chemical analysis; is that fair?
A Say that again. I didn't catch it.
Q Sure.
We do not know what, if anything, would have been shown for the 68 other explants that were not subjected to chemical analysis because the chemical analyses were not done; is that fair?
A We don't know. He didn't report it, for reasons that I'm not entirely sure.
Q And in Clave's paper, am I correct that not all of the polypropylene explants were even -- had physical degradation?
A Yes. But I talked about this earlier, Clave is not trying to report the incidents of -- strike that. He's not trying to report

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frequency. He is saying that he observed it. With what he had, with what he could test, he observed evidence. He doesn't say he observed it in every sample, but he did observe it. That's what he is saying. So he did not observe it in every sample, but we've talked about this.
Q Dr. Clave did report the rate of degradation that he saw in the samples that he actually did analyze, correct?
A He did report that number but --
Q So for polypropylene monofilament at the table at the top of Page 266, do you see that?
A I see that number. I know what you're saying.
Q And you understand the Prolene polypropylene mesh in the TVT Abbrevo to be a monofilament polypropylene?
A Yes.
Q And what Clave found was that only one-third of that sample of polypropylene monofilament that he actually looked at was degraded, correct?
A I look at it a little differently. I look at

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it as, wow, one-third were degraded, that's a lot. That's how I look at it.
Q Regardless of how you want to characterize it, let's see if we can agree to this. Dr. Guelcher, we can both agree that Dr. Clave reported that the rate of degradation in the polypropylene monofilament was one-third or 33.33 percent, correct?
A That's what he reported. But to try to construe that that is a good number is beyond my understanding. That's what he reported. He reported that one-third were degraded.
MR. SNELL: Move to strike. I'm just looking for a yes or no.
BY MR. SNELL:
Q If we can agree to this basic fact. How you characterize it, I know what position you're coming from. All right.
In the Clave paper for the polypropylene monofilament, the rate of degradation seen was one out of three or 33.33 precent, correct?
A That's what's in the table.
Q Fair enough.
And you have your interpretation of that?

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A I do.
Q And let me ask you, if more likely than not it's 51 percent or higher, you can't look at the Clave paper and say it's more likely than not that there would be degradation to polypropylene monofilament mesh, correct?
MR. KUNTZ: Objection. You can answer.
A If I were a patient looking at that number, I would be concerned.
MR. SNELL: Move to strike. Nonresponsive.
BY MR. SNELL:
Q When you look the Clave paper, you can't say it's more likely than not that there was degradation to the polypropylene monofilament mesh, correct?
MR. KUNTZ: Objection.
A I don't even know how to answer that question. I mean, it's -- he reported 33 percent. I will agree that he reported that in this table, in table two, he reports -- or figure two, he reports that 33 percent were degraded. Beyond that, I can't -- that's what he says.

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BY MR. SNELL:
Q So you would agree that Dr. Clave's paper in this table and report, that it's more likely than not that the mesh was actually not found to be degraded, correct?
A I cannot answer that question. That doesn't make any sense. I mean, this is what he reported. To try to construe that -- that's what he reported and what he tested. To try to construe more out of this, this wasn't a controlled study where he was trying to measure race of degradation. He made observations and he reported a number, this percentage that I saw to be degraded.
He was not aiming to estimate some -- he is just reporting. This is the way I read this paper. So I can't answer this question that it's more likely than not on anything. That's just the number he provides.
Q So the Clave paper we can agree does not stand for the proposition that it's more likely than not that polypropylene monofilament is degraded?
MR. KUNTZ: Objection.
A I can't agree to this line of questioning.

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This is -- why can't we not just agree that -- I agree this is what he reported. And beyond that, I'm not going to agree to any other interpretation of that number. That's what he reports. It's an observation saying that this can happen, which is what I've been saying in my trial and deposition testimony, that these events can happen and Clave observed it. That's what it says.
Q So you believe these events of degradation can happen, and Clave observed it in one-third of the sample, correct?
A He observed it in 33 percent of the samples that he tested.
Q And an expert can take Clave and say, because it was seen in Clave, and it was seen in 33.33 percent, that means that all meshes will be degraded, correct?
MR. KUNTZ: Objection. Asked and answered.
A But I've not been saying that. I've been saying specifically that oxidation and degradation can occur in these meshes, and it can lead to adverse events. The timing of when -- these things are unpredictable.

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That's what I'm saying. Unpredictable means you can't predict, and that's a problem. That's why the design is flawed is because you can't predict. The changes can happen, and you can't predict when or the implications of those changes.
My simple point is that Clave sees those events and reports them, but this is not a study designed to investigate the number of meshes that got -- that were degraded. That's not what he is saying. He is observing -- he is reporting an observation. I think you're misinterpreting. You're trying to put me in a position to misinterpret Clave, and I can't do that. I can only report on what I see.
BY MR. SNELL:
Q So you can only report that for the samples that Clave did decide to analyze for degradation, it was 33.33 percent for the polypropylene monofilament, and to try to take that number and extrapolate it is not something you're willing to do?
MR. KUNTZ: Objection.
A When have I done that in trial testimony?

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You've seen my depositions.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q We are going to be here all day. I'm not asking about when did I see you doing something. I'm really not.
A I just feel like you're covering old ground that I've been over so many times, and you're trying to get me to misrepresent a paper that I've testified about so many times. And I don't understand why you're doing that. That's why I'm frustrated.
Q Well, it's a simple yes or no answer.
A But the questions are convoluted. And the way you're asking them is implying certain things. When you say he decided to analyze. Why could we not say, Clave analyzed -- in the number of samples that Clave estimated by SEM, he observed 33 percent of them were degraded. I agree with that. That's what Clave says.
But I don't want to agree to any other questions that infer some kind of intent or something in Clave. That's what I'm resisting. I'm not trying to be difficult.

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I just feel like I have been very clear about what I think about this paper. And I'm just saying that it is consistent with my testimony that these events can happen. That's what I am saying. That's what I have always been saying.
Q I just want to get an answer to my question. You interpret Clave as being consistent with your opinion in that it can happen. And Clave observed it in 33.33 percent, correct?
A Yes, he observed it in 33 percent, that's fine.
Q But you not take Clave and extrapolate Clave to say that a certain rate of degradation will be seen in the mesh samples? Yes or no.
MR. KUNTZ: Asked and answered. Eight times.
A I've not done that and I'm not doing that now.
BY MR. SNELL:
Q Okay. That's all I wanted to know was is that something you would do or would not do.
A Well, where you ended up with the question, I was fine with it. I'm not trying to be difficult. I'm sorry.

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MR. SNELL: All right. Let's take a break.
(A brief recess was taken from 10:40 to 10:50 a.m.)
BY MR. SNELL:
Q Doctor, you didn't look at Mrs. Perry's medical records, correct?
A I did not look at her records.
Q Did you look at any of the depositions taken in Mrs. Perry's case, hers or any of her doctors or family members?
A I looked at some depositions, but I can't remember exactly those -- I don't know.
Q Are you certain that they were depositions in the Perry case or could they have been from some other matter?
A It could have been. There has been so many cases, it's hard for me to keep all of the documents straight.
Q I'm looking at your reliance list, and I gave you this back.
A The reliance list?
Q Your list of materials on there that you provided --
MR. KUNTZ: I will tell you that

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there is no case specific depositions on there.
MR. SNELL: Well, that is what I was going to say.
BY MR. SNELL:
Q So, Dr. Guelcher, I looked at your reliance list. It's on the thumb drive. And I didn't see any case specific depositions, particularly from Mrs. Perry's case. Is that consistent or inconsistent with your knowledge?
A I have -- it's consistent with my knowledge, yeah.
Q You're not relying on any case specific depositions in the Perry case for your opinions are you, sir?
A I am not.
Q All right. Thank you.
A Okay.
Q Earlier we were talking about some testing. And you didn't do any SEM testing on Mrs. Perry's explant, correct?
A No, I did not.
Q Did you have anybody else do any testing of Mrs. Perry's explant on your behalf?

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A I did not.
Q Okay. You didn't do any FTIR testing on Mrs. Perry's explant, correct?
A I did not.
Q Did you do any GPC testing on Mrs. Perry's explant?
A No. The only explant I received was in the form of sections of the slides of tissue, so it's -- I didn't do any of this type of testing on that material.
Q You did not do XPS testing on Mrs. Perry's mesh, correct?
A That's correct.
Q You did not do DSC testing on Mrs. Perry's mesh, correct?
A No.
Q You did not do EDX testing on Mrs. Perry's mesh; is that correct?
A That's correct.
Q Are there any tests besides SEM, FTIR, GPC, XPS, DSC and EDX that someone can do to look for either chemical or structural degradation?
A So Dr. Iakovlev, who has testified in other litigation, not in this particular case I

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don't believe, but he has a microscopic method for evaluating degradation of the mesh by microscopy.
Q Dr. Iakovlev is a pathologist as you understand it?
A He is a pathologist at a hospital in Toronto.
Q And Dr. Iakovlev is not an expert in this case to your knowledge; is that correct?
A To my knowledge. I've not discussed this case with Dr. Iakovlev.
Q Do you know if Dr. Iakovlev has looked at Mrs. Perry's mesh or slides?
MR. KUNTZ: Objection.
A Not to my knowledge.
BY MR. SNELL:
Q Do you know if Dr. Iakovlev's microscopic method for evaluating mesh has been analyzed by any of the pathology medical societies, like the American Association of Surgical Pathologists or the American College of Pathology?
A I don't know the answer to that. But we are preparing a manuscript on explaining mesh that will be submitted soon. And I'm a co-author on that manuscript.

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Q Does this manuscript concern Mrs. Perry's explant to your knowledge?
A I am not aware of Dr. Iakovlev -- strike that. From my perspective, the patients are de-identified. I don't know the identity of any patients in that study. What Dr. Iakovlev knows, I don't know.
Q And were these explanted meshes received by you or Vanderbilt or were they received by Dr. Iakovlev or someone else?
A They were all received by Dr. Iakovlev from varying sources. And all of those details, he knows. I did not handle the specific materials. I was never involved in that.
Q For this testing, who did the testing that is going to be the subject of this manuscript?
A So Dr. Iakovlev did the testing. My contribution was suggesting disdain for myeloperoxidase, which is a marker for reactive oxygen. And that information is concluded and discussed in the manuscript. And I have assisted Dr. Iakovlev with revising and editing the manuscript.
I have made my changes and sent these to him. And that's been my role in the

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manuscript.
Q As you sit here today, is it correct, sir, that you do not know the particular patients for whom those slides were made that are going to be the subject of this manuscript?
A That is correct. I do not know their identity.
Q Okay. Actually, some slides from Mrs. Perry were brought to the deposition today, correct?
A That's correct.
Q Have you looked at those slides?
A I looked at them visually, but I did not look at them under the microscope.
Q Okay. Now, the Perry slides that you looked at visually, how did you come to obtain those?
A Through plaintiff's counsel.
Q You didn't get those through from Dr. Iakovlev?
A No, I did not. Plaintiff's counsel.
Q And you have not sent Mrs. Perry's slides to Dr. Iakovlev, correct?
A I received the slides from Plaintiff's counsel, and they have been in my possession

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since.
Q Okay. When did you receive those slides that are particular to Mrs. Perry?
A A few weeks ago maybe. I don't remember exactly.
Q What is this myeloperoxidase stain that you referenced earlier?
A It's myeloperoxidase. It's spelled M-Y-E-L-O-P-E-R-O-X-I-D-A-S-E.
Q And what is the purpose of the myeloperoxidase stain?
A So myeloperoxidase is an enzyme that converts hydrogen peroxide and other substrates to hydroxl radicals and other forms of reactive oxygen species. And so if we see a stain that is positive for myeloperoxidase, that tells us that the inflammatory cells are secreting reactive oxygen species, that the mesh is being exposed to the reactive oxygen species and would therefore be a marker of this initiation of events of oxidation and degradation. That's the purpose of the stain.
Q Okay. To your knowledge, Mrs. Perry's pathology slides have not been stained with

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this myeloperoxidase stain; is that correct?
A That's my understanding.
Q So as I understand it, the myeloperoxidase stain --
A You can call it MPO.
Q Thank you. That makes it a lot easier.
The MPO stain is a stain that one can do to look for reactive oxygen?
A That's correct. I published two papers on this in my work at Vanderbilt. So it's a routine essay.
Q And reactive oxygen is what these inflammatory cells secrete or can secrete; is that correct?
A So the Dr. Anderson review that's in my reliance materials from the 2008 seminars in immunology teaches that within days of implantation, the biomaterial, including polypropylene, including Prolene mesh, is colonized by these inflammatory cells that adhere to the surface. And the enzymes that they secrete, such as MPO, are these -- result in the formation of reactive oxygen species to which the surface of the material is exposed.

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That's what's happening. That's what I have testified to in the past.
Q Okay. We can't say in Mrs. Perry's case that there is MPO at the site of her mesh, correct?
A I would say that with a reasonable degree of scientific certainty, he's talking about Anderson's 2008 paper. Adherent macrophages, when they adhere, they become activated, and they begin to secrete ROS or reactive oxygen species. And the explants that Dr. Iakovlev has looked at, he has seen myeloperoxidase staining in the ones that he's stained.
And so from a reasonable degree of scientific certainty, I would expect to see myeloperoxidase, but we did not -- those stains, those slides to my knowledge have not been stained for MPO, and so I could not assess that.
Q Is it fair to say you could not assess in the Perry case MPO's presence at the mesh; is that correct?
A I don't think I like the words could not. They could be stained. This work could be done, but that's a decision for plaintiff's

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counsel. So just to clarify your question, the slides as I received them to my knowledge were not stained for MPO, and so that assessment could not be made. It could be possible to do that work, but that's a decision for the attorneys to work out, not me.
Q All right. To your understanding, it could be possible that plaintiff's counsel could have those slides stained for MPO, correct?
A It's a complicated question how these samples are handled, whether or not they're in the right form that it can be done. I would think we would need the blocks to cut new slides. I don't know what material is available. I would say in theory it could be done, but I don't know how practical that is. I don't know the history of the slides, that's the history of the explants.
Q You would not be the one looking at the slides under the microscope if an MPO stain was done in any event?
A I would. I would look at that under the microscope and I would take a picture. My students have done that in the past. But

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this is evidence, I'm not going to just take those slides and stain them for MPO not knowing their history. There are legal ramifications to that. You know, both sides have to agree to testing procedures.
This is a complicated question. All I'm saying is that to my knowledge these are H&E sections. And to assess the presence of myeloperoxidase, they would need to be stained.
Q To assess the presence of MPO, the slides would need to be stained?
A To confirm it. I need to be very clear what I'm saying. Based on a reasonable degree of scientific certainty, my work with Dr. Iakovlev, my reading of the literature, I would fully expect to see positive stain from myeloperoxidase. That has not been visibly confirmed in a section because the slides have not stained for that enzyme.
Q What is the literature that you are referencing with regard to your opinion that you would expect the MPO stain to be positive if it was done in Mrs. Perry's case?
A The paper that comes to mind would be a

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review paper by Professor Jim Anderson at Case Western from 2008 where he cites a very large number of papers in this review.
And he teaches that upon implantation, the surface is colonized by these monocytes, inflammatory cells, that differentiate in the macrophages, foreign body giant cells, and become activated when they adhere to that surface and secrete reactive oxygen species, such as myeloperoxidase or they produce.
Q This work by Dr. Iakovlev, has it been published anywhere that you have seen, in a peer-reviewed journal?
A It's not been published. We're preparing to submit it, the manuscript. It's not been published yet, though. It's still a confidential work product that will be submitted.
Q Do you have a copy of the manuscript on the thumb drive?
A No. It's a confidential work product with Dr. Iakovlev, so we have to maintain strict confidentiality when we submit to the journals so we don't compromise the review process.

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Q Do you know the rate at which the MPO standing was positive in the samples that Dr. Iakovlev did?
A When you say rate, I think you mean frequency?
Q Sure.
A From my understanding, all of the explants that I've seen from Dr. Iakovlev stained positive for myeloperoxidase. So I'm not saying that everything I've seen is positive for myeloperoxidase.
Q These are other litigation explants, correct?
A In some cases. I have seen explants from Dr. Iakovlev for other litigation, and there is also the manuscript. So I should say, the explants that I've seen stain for myeloperoxidase from Dr. Iakovlev. All have tested positive for myeloperoxidase or MPO.
Q Do you have those explants or samples in your possession?
A I do not. That's Dr. Iakovlev's work product. I've seen -- Dr. Iakovlev has sent me images, pictures of the slides that I've included in expert reports in previous testimony.

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Q How large of a cohort is this?
A 130 patients, explants from 130 patients.
Q And this is a cohort for whom you do not know which patients are particularly involved?
A I am blind to patient identity.
Q Okay. Would it be fair to say you do not know which manufacturer's meshes are involved for whichever particular patient in that study?
A I believe that in the manuscript, Dr. Iakovlev mentions some of the devices, but I don't know which device went in which patient. And I don't know if Dr. Iakovlev has that information.
Q As you sit here, you do not personally have knowledge about what device went into which patient?
A I do not.
Q As you sit here, you do not personally know which particular manufacturer's devices were the subject of the 130 patients?
A I believe I have that information. It may be in the manuscript. I just can't remember. I don't remember. That information may be in the manuscript, but certainly I don't know

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which device was with which patient. I would not know that because I don't know the patients.
Q You don't have personal knowledge such that you have confirmed that a particular manufacturer's device was the subject of the 130-patient study, correct?
A Yeah, I can't disclose that right now. I can't even remember it. I'm just saying for the record, it may be in the manuscript, but I don't remember those devices.
Q If it may be in the manuscript, it's something that Dr. Iakovlev would have put in there and not you?
A Yes, that's fair.
Q So you don't have personal knowledge, you've been relying on what Dr. Iakovlev said, if indeed he even said it in the manuscript, correct?
A That's correct.
Q So I guess you would not know if there were any TVT Abbrevos that were the subject of this manuscript?
A I don't remember. But I'm not relying on the manuscript for my opinions in this case,

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because it's not been published yet, and we're not disclosing it, so --
Q Okay.
A You're asking me about my experience with mesh and I'm telling you. That's my understanding.
Q Fair enough.
You're not relying on that manuscript in the 130-patient analysis for your opinions in this case, in the Perry case?
A Yes, I would say those findings confirm my opinions, but I am not relying on them because that manuscript is still a work in progress.
Q So when the inflammatory cell attaches to the mesh or to a foreign body, MPO is one of the substances it can release?
A Well, I would say that MPO is an enzyme in the cell that catalyzes the reaction of substrates, such as peroxides, to form, reactive oxygen species such as, you know, hydroxl radicals, superoxide. There is a very large number of these reactive oxygen species, but MPO is an enzyme that generates those reactive oxygen species.

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Q It's your opinion that the reactive oxygen species produce compounds, chemicals, which has an affect on the mesh?
A So the reactive oxygen species do impact the mesh. They -- through this oxidation chemistry of polypropylene, the tertiary carbon hydrogen bond is subject to attack, and those radicals will attack that bond and oxidize the polypropylene.
Q If the radicals don't attack the bond, does the polypropylene get oxidized?
A It may be other mechanisms. The most well-known is this radical attack.
Q Are you going to come in and testify that there are other methods by which the polypropylene gets degraded besides this, you know, attacking the bond that you've talked about? I don't see it here in your summary of opinions.
A So in my summary of opinions, I discussed the interactions between oxidation and degradation. And my point is that oxidation as we're saying is a very early event. It happens immediately upon implantation. And at some point, the materials become induced,

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and the properties change very dramatically. But degradation can occur prior to induction, and it certainly can occur after induction, so the two processes are related.
The mechanical stresses can certainly impact this as well. That's known as environmental stress cracking. So they are a factor, so you can't separate the two. The mechanical stresses and the chemical stresses are interrelated.
Q You've not seen any embrittlement of Mrs. Perry's mesh, correct?
A I have not tested for it and have not seen it.
Q You've not seen any cracking of Mrs. Perry's mesh, correct?
A Correct. I haven't tested for it and seen it.
Q You have not seen any molecular weight loss from Mrs. Perry's mesh, correct?
A No. I've not tested for that and seen it.
Q Besides the macrophages, are there any other cells that you will plan to testify can release these reactive oxygen species?
A Well, Dr. Anderson teaches that monocytes,

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which are very small mononuclear cells, colonize the implant, and then those cells -- and they adhere to the implant. And when they attach or adhere to the surface of the implant, they become activated. They can differentiate to become macrophages or macrophages can fuse to form foreign body giant cells.
And these cells all come from a common lineage, so they're all inflammatory cells. So when they're adhered, they're activated to secrete ROS. Other types of cells, such as neutrophils, which is commonly seen during acute inflammation or infection, also secrete ROS. So there are other cell populations. Really just many, many types of cells secrete ROS. But in my previous testimony, I was focusing specifically about these adherent macrophages in giant cells.
Q It's fair to say you're going to focus on the adherent macrophages in giant cells in the Perry case?
A Yes.
Q Okay. What happens with the macrophages is -- do they get signaled to the site?

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A So the signaling is very complex and it's reviewed in Dr. Anderson -- and it's just part of the foreign body reaction. When you implant a foreign body, many different types of cells infiltrate that site of injury, and there are various chemical signaling factors that are involved. It's just very complex.
Q Well, let's not go down that road. I was trying to get to a simplistic step-by-step process.
So the macrophages are signaled to the site of the mesh or wherever there would be a foreign body?
A I would say that monocytes are recruited due to the injury, and that mechanism is very complex. But they go to the site of injury, and they adhere to the foreign body.
Q Okay. I guess the question I want to ask is, monocytes in the foreign body giant cells, it's correct that they can persist at the site of a foreign body for years, correct?
A So Dr. Anderson teaches in that review that they're present --
Q Can you answer my question yes or no and then the basis after?

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A Okay. It's just the way you're phrasing it, I don't necessarily want to say yes or -- that's the only problem.
Q All right. Fair enough.
A I want to answer. I just want to make sure that there is a clean record of what I'm saying.
Q All right. So macrophages formed by giant cells can persist at the site of the mesh or foreign body; is that correct?
A Yes, they are there -- again, in the Anderson paper, they are there for the lifetime of the device. They're persisting.
Q And when you say the Anderson paper, is that the one you identified earlier on the record, sir?
A Yes, sir.
Q Okay. Thank you.
Now, isn't it true, Doctor, that those macrophages in foreign body cells that persist at the site of the foreign body can become quiescent?
A I've seen this idea proposed. Again, I'm relying on Dr. Anderson's 2008 review. And Dr. Anderson is a member of the National

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Academy, and his seminal work is in this area of foreign body reaction. And in this paper, he is saying that the cells adhere and become activated. And I know that there is a fair amount of scientific research aimed at this idea of inactivating macrophages. I'm aware of this.
But, again, to my knowledge, the teaching in the field is that they are activated. The work I've done with Dr. Iakovlev is saying that when we see these cells, we see myeloperoxidase when we stain for it. So that's why I'm expressing the opinion with a reasonable degree of scientific certainty that these cells are activated and secrete ROS when they are attached, when they adhere to the foreign body.
Q Did you look for literature that was contrary to your opinion that these cells remain activated?
A I'm aware of work in this area just through my work that I do. I can't think of a specific paper right now. If you have one you want me to look at, I can. I'm just expressing my general understanding in the

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field without any documents in front of me.
Q You're aware of the belief in the field that these inflammatory cells can become quiescent, and they do not necessarily remain activated at the site of the foreign body?
A I don't -- there are ideas that -- I don't know that -- quiescent I think is a strong word. Maybe there are varying levels of activity, but I don't know that I've seen convincing proof that they are just completely quiescent. Again, if you would like me to look at a paper, I will look at one, but this is my understanding.
Q What are lysosomal constituents?
A Can you put some context to that? I'm not -- just to give me a phrase. Lysosomal constituents, I mean, what's the context of it?
Q With regard to foreign body giant cells, whether they remain activated releasing their lysosomal constituents?
A I'm just not -- I could look at something. It's hard for me to answer that just in the way that question is phrased. I would have to look at what you're referring to, because

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I am just not sure what you mean.
Q Did you research the question of whether inflammatory cells become quiescent or deactivated at the site of a foreign body?
A I don't remember specifically doing that for this particular litigation.
Q Are there any books in your field considered authoritative or important to these general principles of foreign body reaction?
A I don't know. There is lots of -- I mean, I've got a book on biomaterials that has -- Professor David Williams has just released a book on biomaterials. There is a book Biomaterials Science by four very well-known senior scientists that discuss these ideas. You know, these are all important books.
Q Let me ask you this. Is there any way to test to know whether the cells are remaining activated?
A Well, that's the myeloperoxidase stain. When I see a positive stain for MPO, that's staining for that enzyme, and that's telling us that the cells are generating ROS. That's how you do it.
Q Is there any other test that you can do that

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would actually show those substances released by the ROS?
A It's more difficult to do because they are such small molecules. The myeloperoxidase is just a very -- you know, it's a relatively straight forward stain to do.
Q Do you know if the MPO stain is recognized by the American College of Pathology as a proper stain for assessing the release of that substance by ROS?
A I don't know. We looked at -- you know, I published this, so it's been peer-reviewed. It was accepted as a marker of presence of oxidative conditions.
Q Does Dr. Williams' paper that you referenced state with certainty that those macrophages of foreign body giant cells continue to remain activated and release substances on the surface of the biomaterial?
A I think you're getting papers confused. I was referring to the Anderson 2008 paper.
Q Okay. I'm sorry. So let me just ask a better question. Anytime you need to the correct me, let me know. I get these things confused.

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A I understand.
Q In the paper by Jim Anderson, does he state that those macrophages in foreign body cells continue to release the substances at the site of the foreign body as years continue to progress and they remain activated? Is that conclusively stated in the paper?
A So I'd like to answer that by stating what Dr. Anderson does say in that paper. He says that the cells become activated, and that the foreign body reaction is present throughout the lifetime of the device. And then he qualifies that as, albeit, in some cases at a low level.
So what he is saying, and then what his point is, is that as long as the device is there, this foreign reaction body is ongoing, and that these factors need to be considered in the design of the medical device. That's what he says.
Q Okay. So Dr. Anderson does not state that if the cells are there, they are going to be activated and producing these substances?
A I would say it's implied. It doesn't necessarily specifically state that. And I

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would be happy to read it from the paper, but it's very strongly implied that that's what's happening in the way that it is stated.
THE WITNESS: I have to go to the bathroom if you don't mind.
MR. SNELL: Let's take a break.
(A lunch recess is taken from 12:00 to 12:50 p.m.)
THE COURT: Let's take a break.
BY MR. SNELL:
Q Doctor, we are going to mark the Perry pathology slides that you have in your possession as Exhibit No. 2.
(Deposition Exhibit No. 2 is marked for identification.)
BY MR. SNELL:
Q And I will hand you Exhibit 2. Just confirm for the record that those are the slides, sir.
A Yes, these are the slides I was presented.
Q It looks like there is three different sets, each of them wrapped in bubble wrap?
A Yes.
Q Am I correct, sir, that you're not relying on those pathology slides for your opinions?

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A That's correct.
Q Do you know what type of inflammatory cells, if any, are present in Mrs. Perry's mesh?
A I don't know. I didn't look at the slides under a microscope.
Q You therefore would not know how many of any inflammatory cells, if they are present, were actually there, correct?
A That's correct.
Q When we were talking about the inflammatory cells, just so we're on the same page, I'm referring to the macrophages in foreign body giant cells?
A Yes.
Q Okay. So when we say chronic inflammatory cells --
A Yes.
Q -- are we talking about macrophages in the foreign body giant cells?
A Yes.
Q Okay. Do you know whether there were any chronic inflammatory cells present in Mrs. Perry's vaginal tissue before her surgeries, one of which included mesh?
A I'm not aware of that information.

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Q Did you attempt to look at any of the pathology reports in Mrs. Perry's case?
A No, I did not review those reports.
Q Have you attempted to measure any of the reactive oxygen species in Mrs. Perry?
A We talked about this earlier. I didn't do that.
Q Have you attempted to do any mechanical testing of Mrs. Perry's mesh?
A No.
Q Are you aware of any testing done on Mrs. Perry's mesh to determine whether it became tougher after implantation?
A I'm not aware of any other testing on her mesh.
Q And you would not have done such testing to determine whether it became tougher, correct?
A Seems like -- I'm not sure what you mean by the mesh became tougher. I mean, it seems like it would be difficult to do.
Q You could test to determine whether the mesh became embrittled in Mrs. Perry, correct?
A Test the outer layer, that could be done by a nanoindentation. But, again, you need an appropriate amount of mesh in the right form.

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It's not going to work on a histological section. You would need mesh from the patient before it's been processed for histology to do those measurements.
Q You said that was nano --
A Nanoindentation could measure the brittleness of the surface degraded layer.
Q Is that a particular type of test, nanoindentation?
A It is.
Q Is it separate and apart from some of the other testing that we've discussed?
A It is. It is mechanical testing at a very small scale. I've done testing like this with a collaborator at Vanderbilt where we probed the surface with a cantilever beam, and we measure the response and the mechanical force. You can measure an elastic modulus doing this.
Q You have not done any of this nanoindentation testing on Mrs. Perry's mesh, correct?
A That's correct.
Q Have you seen any photographs of Mrs. Perry's mesh that showed cracking?

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A I've not seen any photographs of her mesh.
Q Earlier you were talking about the bonding that can occur leading to degradation of the particular atom. I don't recall if it was carbon or hydrogen.
A You are referring to oxidation and a free radical attack on a tertiary carbon hydrogen bond?
Q Yes, sir.
A Yeah.
Q So for oxidation, is that oxygen which comes and bonds with carbon or the other way around?
A The details of the reaction are very complex. But, essentially, it's a radical attack, a hydroxl radical or oxygen radical can attack that bond. The chemistry is very complicated.
Q What is the difference between an oxygen molecule and an oxygen radical?
A Well, it's just the nature of the chemical reaction. In the body -- and in our in vitro testing -- I can speak specifically from our in vitro testing, the solution that we created generated hydroxl radicals, and those

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hydroxl radicals attacked that carbon hydrogen tertiary bond -- tertiary carbon hydrogen bond.

The hydroxl radicals attacked that bond, and that's where the pollen becomes oxidized. And then there is a number of steps in this reaction, I would have to look at a paper to explain it, but there is just a number of steps in that chemical reaction. It's very complex.

Q When you say the hydroxl radicals attacked the bond, is that that tertiary bond you were referring to?

A Yes. It extracts the -- I would have to look at the paper to show the exact mechanism, but that tertiary carbon hydrogen bond is vulnerable to an oxidative attack. But the physical chemistry of that reaction is, again, complex.

Q Is it correct that you have not seen the presence of a hydroxl radical in Mrs. Perry's case?

A Yeah. As we have discussed before, I have not done the myeloperoxidase staining or looking for a radical, which would be very

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difficult to do in her case. I have not done that.

Q As I understand it, the presence of hydroxl groups on a surface would be indicative of oxidation?

A It's the OH group forms in a hydroperoxide intermediate. There is a hydroperoxide that forms on the oxidized polypropylene, and we can see that peak by IR spectroscopy.

Q Have you attempted to do any IR spectroscopy in Mrs. Perry's case?

A No, I have not done that.

Q As I understand it, there is testing that can be performed to try to assess atomic percents, such as the percent carbon, percent oxygen, and percent nitrogen; is that correct?

A There is a method called x-ray photoelectron spectroscopy. We will call it XPS. XPS tells us what percentage of the carbon is bound to other atoms. So in pure polypropylene, all of the carbons should be bound. Either the hydrogen or carbon, it's a hydrocarbon. When polypropylene becomes oxidized, we see the formation of

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carbon-oxygen bonds that we can detect by XPS.

Q Have you attempted to look for the presence of carbon-oxygen bond in Mrs. Perry's case?

A I have not done that.

Q Have you attempted to look for the percent of carbon in Mrs. Perry's mesh?

A I have not done that.

Q Have you attempted to look for the percent of oxygen in Mrs. Perry's mesh?

A No.

Q You earlier mentioned different biomaterial books, one of which was your own, I believe?

A I edited a book, Introduction to Bond Materials. It's on my CV.

Q What biomaterial books are used at Vanderbilt?

A So the BME department -- I mean, chemical engineering department, the biomedical engineering department, teaches a course in biomaterials. I'm not sure what they're using now. In the past, they have used a book by Johnna Temenoff on biomaterials. I think they have made some changes to that course. I've never taught that course, so I

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don't know all the details.

Q Is your book used in teaching biomaterials at Vanderbilt?

A Not to my knowledge. But that book was written for a somewhat different purpose than for a teaching textbook.

Q I think earlier you mentioned another book called Biomaterials Sciences, and it had a couple of different editors or authors?

A So there were two well-known books. The older one is -- well, I think it's called Biomaterials Sciences. It was -- maybe endorsed isn't the word, but the Society for Biomaterials endorses this book. Endorses may be a strong word. They recognize this book as being an important book, and there are four senior authors on this book.

It's written more as a reference text. It's difficult to teach from, because it's an edited book. So it's an excellent resource for study. But for teaching undergraduates, it's not as accessible. So Professor David Williams, who is also a lead world expert in biomaterials, has written a new textbook. I

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contributed some figures to that textbook.
And Professor Williams' textbook has been assessed by my colleagues in BME at Vanderbilt for teaching. I'm not sure if they've made a final decision whether to use it. What's attractive about that book for teaching is it's written by one author. So it's a single-author book, and so this is good for teaching undergraduates.
My textbook, I edited, so there are chapters by individual contributors. So it's just a different book.
Q When you were going about compiling your book, did you reach out to people who you felt were experts in certain fields to write or contribute to particular chapters?
A That's how we approached editing the book, that's right. That was in 2005 when I was a postdoc.
Q What is the most recent edition of your book? Is it on your CV?
A Well, I co-edited the first edition. There is a second edition, but I didn't co-edit that one. The only one that I have co-edited has been published in 2006. It's on my CV.

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Q The Society for Biomaterials, you referenced you're a member of that society?
A I am.
Q And the book they recognize as being an important book is Biomaterials Sciences. Is the title An Introduction to Materials and Medicine by --
A That sounds right.
Q -- Buddy Ratner?
A Buddy Ratner, Hoffman, Schoen. They're all founders of the Society for Biomaterials, very well-known. Jack Lemons is the other author.
Q Did any of those authors contribute to your book?
A I don't remember. I don't think so.
Q I want to ask you some questions about TVT Abbrevo. I'm just trying to give you an idea of where I'm going.
A Okay.
Q Because I know we went back and kind of covered some things that we addressed earlier with further questions.
A Okay.
Q Have you done any testing of any type on TVT Abbrevo?
A I have not.
Q Have you done any testing of any type on TVT product for stress incontinence? And when I stay TVT, I mean Ethicon's particular TVT product.
A So only the testing performed at Dr. Dunn's laboratory. Just to be clear, Dr. Dunn did that testing. I consulted and advised. We discussed it, agreed to do it, but Dr. Dunn physically performed the testing.
Q Tell me what testing did Dr. Dunn do on an Ethicon TVT device. As I had read -- and I'll tell you why I'm asking. As I had read your Huskey deposition testimony, he had done some testing on maybe one or more AMS meshes and Boston Scientific meshes.
A These are new testing that we've done.
Q Let me just back up then. So as I understand it, Dr. Dunn has done some testing on Ethicon TVT products?
A Yes.
Q Are you relying on that testing for your opinions in the Perry case?
A Let me look at my opinions for a minute.

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Yes, I am relying on that testing. So I should say, I formed my opinions based on the literature review. My opinions are the same as they were in the Huskey case on this particular topic of oxidation and degradation, and this testing further confirms my opinions.
And the testing was specifically done to answer the question that Ethicon raised during the trial in August, that Prolene is different from polypropylene and doesn't oxidize because it has antioxidants.
So in the testing done by Dr. Dunn, the goal was to answer the question can Prolene in a TVT device oxidize and degrade. And we saw oxidation and degradation of the surface pitting in that testing, in the oxidative medium that I was describing earlier. So the testing was performed to answer a very specific question of -- and to answer the specific question of can the Prolene polypropylene oxidize. That was the purpose of the test.
Q Where is this testing, all of the notebooks, the results, the data generated from it that

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you are relying on?
A So this is on the disk that was provided.
Q Okay. Show me where on the disk that that is this TVTG testing is located.
A I don't have a computer but --
Q Can you use Mr. Kuntz'?
MR. KUNTZ: He can.
Let's go off the record for a second.
(Off-the-record discussion.)
BY MR. SNELL:
Q Counsel is looking at the thumb drive. Obviously, I can't look at it and question the witness about 6,000 files today. Let me just get some basic information about this testing.
The testing that was performed on Ethicon's TVT mesh, what specific device or devices were the subject of the testing?
A I believe it was the TVT.
Q The original TVT retropubic?
A I believe so. And we also tested an unstabilized polypropylene controlled, it had no antioxidant.
Q Okay. You said it was an unstabilized Prolene polypropylene?

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A No. It's polypropylene without antioxidants. So it would be the equivalent of -- in the Liebert paper where they tested the monofilament with no stabilizers. It's a polypropylene that has no antioxidants. So it's unstabilized polypropylene I would call it.
Q So you didn't test the TVT retropubic mesh with antioxidants to the TVT retropubic mesh with antioxidants?
A No, we can't get TVT without the -- the TVT is made from Prolene that has that Prolene antioxidant package, because that's what we tested, that's what we could get. So we had that exemplar, Dr. Dunn had it, and we compared that to the unstabilized polypropylene. We also tested two Boston Scientific meshes, but that's not in the materials that we presented. That's different.
Q You are not relying on this Boston Scientific testing for your opinions in this matter, correct?
A I am not.
Q Okay.

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A I am just disclosing what we did.
Q This TVT retropubic device that Dr. Dunn tested, was it one single device or was it a batch or numerous ones?
A I believe it was one device with three replicate pieces, three distinct pieces cut from -- it was three or four. I can't remember the details. I would have to look at it. But there were multiple replicates cut from the same mesh.
Q And the unstabilized polypropylene control, where was that obtained from?
A I would have to look at the document to look at the documents for the exact source, but it was purchased from a third-party vendor that sells polypropylene with antioxidants, unstabilized polypropylene.
Q Do you know the vendor?
A I can't remember. It's in the documents. I would have to find it.
Q Do you know who purchased this control?
A Dr. Dunn purchased it and did all of this work.
Q You personally were not the one who did any of this testing on the TVT retropubic device,

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correct?
A No. As I said previously, Dr. Dunn and I consulted, and Dr. Dunn did all of the work physically through his company.
Q So am I correct that you did not do any of the physical testing of this TVT or the control?
A That's right. Dr. Dunn did.
Q And that was done at his company?
A Yes.
Q Was that testing done out of his house?
A I don't know. Maybe some of it was done from his house. I don't remember.
Q Do you know where the testing took place on this TVT retropubic compared to the polypropylene control?
A It was done in his lab at Vanderbilt.
Q Who paid for the testing that Dr. Dunn performed comparing the TVT retropubic to the unstabilized polypropylene control?
A I should clarify that all of these responses I'm telling you to the best of my knowledge. And if Dr. Dunn contradicts what I'm saying, it's because I didn't remember it correctly. I believe that this testing was billed to the

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litigation, but Dr. Dunn would have to confirm that.
Q Is your basis for your testimony in that regard something that Dr. Dunn told you?
A Yes, I'm basing it on -- I have not seen those invoices. That would be between Dr. Dunn and plaintiff's counsel.
Q Did Dr. Dunn physically do all of his testing?
A Again, I believe that he did, but I don't know the details of -- he would be the one that would have to speak to that.
Q Unfortunately, he is not identified as an expert here.
A I understand that.
Q Were you present for any of the physical testing of the TVT retropubic or the unstabilized polypropylene control?
A Was I present?
Q Present meaning on the premises where the testing was performed, such that you could yourself observe the testing.
A Well, the testing was just very simple. Dr. Dunn placed the -- I'm trying to answer your question as best I can. So Dr. Dunn

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placed the specimens in vials. They were weighted down with glass beads in this oxidative medium that I was describing that simulates the environment between the adherent inflammatory cells and the biomaterial. I have seen those vials.
And then at different time points, Dr. Dunn removed the test specimens, rinsed and dried them, and measured RI spectra. And I've seen those dried specimens. I've seen the specimens, and so I have seen aspects of the testing, but I didn't watch him do the testing. But the testing essentially involves incubating the material in a solution, and then taking it out and testing it by FTIR and SEM.
Q When was this testing on the TVT retropubic device done?
A September and October of 2014.
Q And it was on a single TVT retropubic exemplar, meaning that mesh had not been in the body at all?
A That's correct.
Q When did you first discuss with Dr. Dunn this testing on the TVT retropubic exemplar?

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A Same time frame. Maybe August -- it would have been September of 2014 after the Huskey trial. And, again, the motivation for the tests was based on Ethicon's statements during trial that we had not tested it and couldn't -- we could not say definitively that Prolene polypropylene oxidizes, and that was the motivation for the test.
So this is what was said in Huskey trial, we decided to do the test to answer that specific question, can Prolene polypropylene oxidize.
Q Now, Dr. Dunn's Vanderbilt lab, is that on the premises here at Vanderbilt?
A Yes, his lab is at Vanderbilt.
Q Do you know if any graduate students or other people were involved in the testing?
A Dr. Dunn has employees. I know that. To what extent they were involved in the testing, I can't speak to. Again, Dr. Dunn just did all of his. I don't know those details.
I should qualify my comment. Dr. Dunn does not have employees, but I know that he does pay contractors for services like he

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pays me. But, again, I cannot speak to how he conducts his business.
Q Why did Dr. Dunn choose to test only one TVT retropubic device?
A That was what we had at the time. And we knew these depositions and report deadlines were approaching quickly, so we moved forward with what we had.
Q Would you have preferred to have more than one TVT retropubic to test?
A We requested additional exemplars from plaintiff's counsel. My understanding is that this is a complex request and takes time. We have requested additional items recognizing the need to test multiple meshes. But as I said, these requests can take time to process, so we tested what we had.
Q Why is there a need to test multiple meshes?
A I should qualify my answer I need to test. By testing multiple products, it's possible to show that it would happen in many of these products. It's not possible to test every one. But considering that the oxidation of polypropylene is due to the inherent

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intrinsic molecular structure of polypropylene, as well as the antioxidant package, if those things are all the same, you would expect a very similar response.

Like I said, it's a chemical reaction. So if it's the same material with the same antioxidants, you would expect to see a very similar chemical reaction. We tested two Boston Scientific meshes because we had to. If we had had more, we could have tested more and would have liked to have done that, but we were limited to what we had at the time.

MR. SNELL: I'm going to move to strike the part about Boston Scientific.

A I understand. I shouldn't have said that. I'm sorry.

BY MR. SNELL:

Q So you would expect to see a similar response you said, correct?

A Yes.

Q If you tested multiple meshes, correct?

A I would.

Q But we know from the teachings of Clave that not all findings will be consistent with regard to degradation, correct?

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MR. KUNTZ: Objection.

A I think that the conditions are very different. Clave is in vivo explant, so there are many different factors affecting oxidation. This study was purely isolating the chemical reaction. The medium that we used has been published by a number of investigators, including me, that simulates the oxidative conditions in the body.

So we're simulating a chemical reaction, not -- there is no cells. There is no tissue. It is simply examining that chemical reaction, will that chemical reaction cause a change in Prolene polypropylene. That was the purpose of the test, so it's very different from, say, Clave's study. It is very specific.

That is why I would expect to see the same changes in any mesh that we tested.

BY MR. SNELL:

Q So this study done in a lab is not under the same conditions as one would see in vivo?

A I wouldn't -- I would qualify that -- there are two papers in my reliance materials by Dr. Jim Anderson from 1990 and 1993 in the

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Journal of Biomedical Materials Research. In the 1990 paper is a seminal paper where Dr. Anderson discovered the effects of the foreign body reaction on a biomedical device.

The 1993 paper he simulated. He reproduced or recapitulated that same oxidation and degradation in that same biomaterial in vitro outside the body. So he was able to show that this solution, this oxidative solution that I've been talking about recapitulates the oxidative conditions that the biomaterial was exposed to in vitro.

I should qualify my previous comment when I said there is no cells. There is no other cell populations like fibroblasts that are exerting contractile forces. There is no tissue that is exerting forces. So this test is isolating the effects of chemical oxidation and was found to agree with in vivo observations. That's the purpose of the test, and those two papers have shown that.

So I hope I'm answering your question. It reproduces certain aspects of the reaction, but not every -- but the ones that I just mentioned.

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Q The test that was done on the TVT device does not establish that an oxidative condition occurs in vivo; is that correct?

MR. KUNTZ: Objection.

A Let me -- the in vitro test does not establish the in vivo conditions. It's recapitulating those in vivo conditions. We know that this happens in the foreign body reaction, and so the test is designed to recapitulate that foreign body reaction in the laboratory.

Q What are the limitations to the test as it was conducted by Dr. Dunn utilizing only one TVT device?

A Well, the limitation of the test is -- I want to be very careful about my opinion. The question we were asking was -- and what I was presented with in trial, and I believe what Dr. Shelby Thames testified for defense was Prolene polypropylene doesn't oxidize. It's stabilized. It's different. It's Prolene. So we asked a very simple question, can Prolene polypropylene oxidize.

We tested one mesh. And we showed that in that one mesh that we tested, Prolene

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polypropylene oxidized. We have also showed evidence of pitting and surface degradation. So the limitation would be, we're not saying that we saw it in every mesh, we're not saying we saw it in 10,000 meshes. We're saying we saw it in one mesh. And we answered this question that it can oxidize. Because it's a chemical reaction, I believe we would see it in other meshes if we tested those, but I recognize that we didn't. We tested one mesh, but we did show that it can happen in that one mesh.

Q So with that said, let's go back to my question. What are the limitations of the testing that Dr. Dunn did given there was only one TVT mesh?

MR. KUNTZ: Objection, asked and answered.

A I thought I answered it. I will try a briefer answer. The limitation would be that we tested one mesh. We showed that it can happen. We did not estimate a probability that it would happen. We tested one mesh and saw that it happened in that mesh that we tested.

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I believe the literature teaches with a reasonable degree of scientific certainty that it would happen in other meshes because presumably they are chemically the same. I didn't look at necessarily the manufacturing doc, but I would presume based on my industry experience that there are specifications for antioxidants and Prolene. I've seen some documents showings those numbers. Provided those compositions are the same, I would expect to see a very similar result, because it is a chemical test testing the effects of a specific chemical reaction.

BY MR. SNELL:

Q Is it fair to say that one of the limitations with that test is that it does not establish that Prolene polypropylene degrades in vivo?

MR. KUNTZ: Objection.

A I would say it doesn't establish the timing in which Prolene polypropylene oxidizes in vivo. The time scale at which this happens would depend on many other factors, the environment, the patient, I understand that, but I do believe that it shows that it would oxidize. It's just the timing of those

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events.

It starts to oxidize immediately when it's implanted. It's colonized by macrophages. I believe with a reasonable degree of scientific certainty it will start to oxidize upon implantation. When it becomes induced, and there are much more dramatic changes in physical properties is unpredictable, as I've said in previous testimony. Those events are unpredictable.

But I do believe that the test tells us that the mesh can oxidize, and I would expect it to oxidize under in vivo conditions due to the nature of the inflammatory response that we discussed.

MR. SNELL: Move to strike.

BY MR. SNELL:

Q One of the limitations to the test that Dr. Dunn did on the single TVT retropubic device was that it does not establish that Prolene polypropylene degrades in vivo; is that correct?

A It does not establish? I'm having a hard time with this word establish. It supports my opinions that these meshes are -- can

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oxidize and degrade in vivo.

Q I'm not asking you whether your interpretation as to whether it supports your opinion.

MR. SNELL: So I would respectfully move to strike.

BY MR. SNELL:

Q The limitation to this test that Dr. Dunn did on the single TVT is that it does not establish that Prolene polypropylene degrades in vivo; is that correct?

MR. KUNTZ: Objection. He said the exact same opposite.

A I'm struggling with the way you phrased the question. I don't want to agree to that. I believe with a reasonable degree of scientific certainty that this test predicts susceptibility to oxidative degradation. And if we see it in vitro, we will see it in vivo.

It's just the timing and the severity are unpredictable, but I do believe it will happen. I think that it's -- the timing and the severity, the clinical consequences are unpredictable. That's what I've been saying.

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MR. SNELL: Well, I respectfully move to strike again.
BY MR. SNELL:
Q Again, I'm not asking you about susceptibility to oxidation, and I'm not asking you about oxidation, that particular step. I'm asking you about degradation in vivo.
So the question again. One of the limitations to those tests by Dr. Dunn on the single TVT is that it does not establish that Prolene polypropylene degrades in vivo; is that a fair statement?
MR. KUNTZ: Objection.
A You're speaking specifically of degradation?
BY MR. SNELL:
Q Yes, sir. That's why my question only said degradation.
A Okay. I would like to explain my answer on this.
Q Can you first agree or disagree and then please feel free to explain?
A So you're saying that it does not establish that it degrades --
Q I will ask it one more time.

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A I'm trying to give you an accurate answer, and I'm struggling with how to answer this.
Q One of the limitations to the test that Dr. Dunn performed on this single TVT retropubic device was that it does not establish that Prolene polypropylene degrades in vivo; is that a fair statement?
MR. KUNTZ: Objection.
A I just don't know if I can agree to that. I believe it -- it -- we didn't see -- I'm just having a hard time with this sentence. The way you phrase it, I would need to move on, so I will leave this for the attorneys later. But the way you are phrasing that question, for now I will agree to it. But I have reservations, because I don't believe it captures what I'm really testifying about.
BY MR. SNELL:
Q It is a simple fact, isn't it, Doctor, that this test that Dr. Dunn performed on the single TVT device, it is not an in vivo test? Can we agree to that?
A I will agree that it is not an in vivo test.
Q There were no macrophages put on the TVT retropubic device and this test that Dr. Dunn

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performed; is that correct?
A You're misunderstanding the purpose of the test.
Q Sir, you have to listen to my questions and answer them yes or no or whatever. I'm not asking you about the purpose of the test and all of that.
A That cannot be answered by a yes or no question. The macrophage is not there, but the consequence of the macrophage is there. That's the test.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q What macrophage --
A I'm not going down on this. Go ahead. I'm sorry.
Q Were macrophages present in the test that Dr. Dunn did on the single TVT retropubic?
A Macrophages were not present, but what macrophages produce, meaning radicals and reactive oxygen was present. We generated those reactive species using a chemical reaction instead of a macrophage, but this is an acceptable accepted approach to doing that.

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Just because a macrophage was not there doesn't mean -- it's the same oxidative conditions. It's just accomplished through a different chemical reaction.
MR. SNELL: Move to strike everything after macrophage was not present.
A I'm not going to back down. We can stay here 'til 5:00 arguing about this. I'm not going to back down the test.
BY MR. SNELL:
Q Sir, we are going to be here multiple days. I can tell you that now.
A Fine. But I'm not -- you're trying to put words in my mouth.
Q No, sir.
MR. KUNTZ: We're not going to be here multiple days. We'll get your seven hours and we'll stay here as late as we can. So --
MR. SNELL: No. First of all, you produced 6,000 pages.
MR. KUNTZ: It doesn't matter. That's the rules under California. We have no obligation to produce at the start of his depo materials he relied on. There is no

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obligation under California state law to do that. We have complied. We have brought a disk and brought the materials responsive to the deposition. That is the only thing that is required under California law. I want to make this clear. We have no duty to produce before the depo anything, zero.

MR. SNELL: That's fine, if that's your position.

MR. KUNTZ: Okay.

BY MR. SNELL:

Q Am I correct, sir, that there were no foreign body giant cells that were used in Dr. Dunn's test?

A My answer is the same. The cells weren't there, but the reaction products were.

MR. SNELL: Move to strike after the cells were not there.

A These are unreasonable questions. And this deposition is going to get more hostile if you keep going down this line of questioning, just to put it out there.

Q Sir, as the witness, I'm allowed to ask you questions. You may not like the question, but you have to answer the questions.

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A But the questions are being phrased that you're trying to misrepresent my testimony and misrepresent what I'm saying.

Q I'm not trying to misrepresent your testimony.

A You are.

Q I'm asking you a factual question.

A And the question is --

Q Was there a horse in the room at the time of the test, yes or no? No.

Was there a macrophage in the test, yes or no?

The interpretation, I will get to that, but I have simple questions, sir, and I'm entitled to simple answers if they're simple questions. You can talk to Mr. Kuntz all night long about your interpretation. That's fine. But I'm actually going to ask you about your interpretation too.

A And I'm entitled to answer questions as I need to. And I'm not going to be put into this difficult position of having things recorded as my testimony that's not what I've ever been saying.

Q You would agree that -- let me back up. What

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is it that you believe this test on this single TVT device compared to the control shows?

A I believe that it shows Prolene polypropylene used to manufacture the TVT device can oxidize and degrade under oxidative conditions similar to those experienced in the human body after implantation.

Q What documents or files out of those 6,000 plus show the oxidation?

A The oxidation is evidenced by FTIRs spectra that were measured in weeks zero, one, two, three, four and five. In the FTIRs spectra, we saw minimal hydroxl and carbonyl peaks until week five, where we saw a significant increase in the magnitude of the hydroxl and/or carbonyl peaks, which was indicative of a chemical induction.

Q So what are the file names and the documents that showed this out of the 6,000?

A I don't remember the file names.

Q Well, I'm entitled to know them.

A I know. And I have to look at it. I don't have it here with me. I know that you're entitled to have it, but I don't have it here

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in front of me.

MR. KUNTZ: He does have it.

MR. SNELL: Out of the 6,000, you think I am some kind of scientist and can pick out this FTIR testing?

MR. KUNTZ: The rules are the rules, Burt. You gave us testing two weeks before trial. I don't cry about it. We follow the rules.

MR. SNELL: All I'm asking him is to identify it.

MR. KUNTZ: That's fine. We'll sit here and he can identify it. Let's pull it up.

MR. SNELL: That's what I thought we were doing.

MR. KUNTZ: If that's how you want to spend your seven hours with him, let's do it.

MR: BOWMAN: There is a folder named FTIR on the drive that was given to you. It's already been disassembled and separated out. There's FTIR, and there's SEM, and XPS.

MR. KUNTZ: I'm trying to get

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you a link, so you can pull them up.
BY MR. SNELL:
Q What documents, if any, in this study that Dr. Dunn did on the single TVT device show that the Prolene polypropylene degrades?
A There are SEM images at weeks zero and five, I believe. What the name of that file is, I don't know. I will have to look at the folders to try to find it.
Q Okay. And what is it about those SEM images that you believe shows degradation?
A There are changes in the surface, including pitting, flaking, changes to the surface that can be observed by SEM.
Q How deep is the pitting?
A I don't know. I would have to look at the image again to see it.
Q How much material is flaking off?
A Again, I would have to look at it to see that. We saw SEM is -- we were just really looking to see if it's there or not. It's difficult to be more quantitative as we can be with the FTIR, but we saw evidence of changes to the surface.
Q Did you attempt to quantify the pitting?

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A We were working on it. In the amount of time we had to pull this together, we haven't had time to do it yet.
Q You attempted to quantify the amount of flaking?
A Same answer.
Q Not yet?
A Not yet.
Q Is there anything else about this test that Dr. Dunn did on the single TVT device?
A Anything else that -- I'm sorry. Go ahead.
Q That's okay.
A It shows degradation.
Q It shows degradation besides the SEM images?
A No, degradation was assessed by SEM.
Q Oxidation was assessed by FTIR?
A That's correct. And there was XPS testing for some of those samples as well.
Q You said there was XPS testing for some of the samples. What do you mean?
A Well, I didn't say that very accurately. I can't remember all of the time points at which we ask did XPS. I know we did FTIR at zero, one, two, three, four and five. We did SEM at zero and five, but I can't remember

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the time point at which we did XPS. It's in the data. I just can't remember it.
Q What, if anything, did the XPS show?
A The XPS revealed the evidence of carbon-oxygen bonds on the surface of the TVT.
Q How many carbon-oxygen bonds were seen?
A So XPS, we did three distinct measurements at three surfaces on the fiber. We cannot see microscopically where we're testing, so it's not possible to tell whether we're testing where there is an area of active degradation or not. Does that make sense?
There is areas of pitting on the fibers, and then there is areas on the fibers that we don't see the pitting. When we do the XPS measurements, we're not exactly sure of where on the fiber we're probing. We actually picked three spots. And the XPS measurement tells us at that particular spot that is being probed, what the percentage of the carbon is bound to oxygen. And we saw many spots. It's in the data. I just can't remember the exact numbers, but we saw many spots on the surface where we saw the

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existence of carbon-oxygen bonds.
Q Should there be no carbon-oxygen bonds?
A There should be no carbon-oxygen bonds in nonoxidized polypropylene, polypropylene that has not been oxidized. I don't want to use pure, because there is other additives. But polypropylene that has not been oxidized should not reveal evidence of carbon-oxygen bonds.
It's similar to FTIR, except FTIR is telling us the functional groups, and XPS is telling us the types of bonds.
Q Were there any inconsistent findings in this test done by Dr. Dunn?
A Not that I'm aware of.
Q Did you put this -- the unstabilized polypropylene control, what was that control?
A It was a polypropylene pellet that was purchased from a third-party vendor. I don't remember the name of the vendor, but I believe it is in Dr. Dunn's testing documents where the polypropylene has no antioxidant added to it.
Q Are the documents in there that reflect what type of polypropylene pellet and where that

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pellet was from? Is that in the files?
A I believe that it is. If it's not, we can get that. That's a known. Dr. Dunn has that information. And I should note that Dr. Dunn has all of the samples from this testing as well. We still have the material. We saved everything.
Q Is it kept at his lab or his house?
A I'm not sure where he is storing that, but he has stored that in dark containers protected from the light. He can speak to that. He's storing the material. I'm not sure where.
Q So this polypropylene pellet that was used as an unstabilized control, am I correct that it had not been extruded or gone through any manufacturing process whatsoever?
A I believe that it had probably at least been extruded because we bought it as pellets. So my understanding is they melt the polypropylene -- I don't know the answer to that. Dr. Dunn would be able to talk about the history of the sample.
Q Do you know if this polypropylene pellet that you tested was a pellet used in any stress incontinence sling devices?

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A I have no way of knowing that without knowing the supplier of the pellet.
Q How was it that Dr. Dunn came to decide on which particular polypropylene pellet from a certain manufacturer he was going to obtain?
A So in his previous testimony, Dr. Dunn has investigated a number of polypropylene cases, and he's done similar testing before in which he used unstabilized polypropylene controls, so that decision would have been based on his experience with prior testing.
Q The unstabilized polypropylene control, what tests were done that on that?
A The same tests as were done on TVT. So it would have been XPS, FTIR and SEM.
Q Did you attempt to calculate any clinical significance of any findings in this test that Dr. Dunn did?
A We are still doing the quantitative analysis, but we will calculate -- how shall I say this -- statistical significance between groups as a function of time. So we would compare the TVT group to the unstabilized polypropylene group. We would compare at each time point. And we would compare within each group at

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each time point because we have three or four replicates.
I can't remember the exact number, but we have enough replicates that we can speak to the significant differences between groups as a function of time.
Q But that analysis has not been done yet, correct?
A It has not been done because we are still quantifying the results.
Q Who will do the testing for clinical significance?
A I don't know yet. We're still discussing this.
Q Who are you considering to do statistical significance testing in this test --
A Dr. Dunn or I. One of us will do it.
Q Are you a statistician?
A I'm not a statistician, but I've done similar statistical testing in any papers that I've published where we compared differences between material groups and time using a one- or two-way ANOVA. That's a common method.
Q But you're going to be testing over different time points, correct?

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A You mean statistically?
Q Yeah.
So you will be testing over multiple time points, correct?
A Yes.
Q So, therefore, you will need to apply a Bonferroni or some type of multiple testing equation, correct?
A Yes. We typically do this. I believe it will be a two-way ANOVA with a Bonferroni correction. But, again, we haven't decided that yet.
Q So as you sit here today, you cannot state that the test results were statistically significant upon applying the proper statistical testing?
A We haven't done it yet. The differences appear to be large, but we have to do the statistics for the FTIR testing. I don't know what we will be able to do yet on the SEM. We are discussing that.
Q So the FTIR testing is the testing that you intend to do statistical significance testing upon?
A Yes.

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Q And the SEM images, because you only took them at limited time points, zero and five weeks, you do not know whether there is enough data to generate statistical significant findings?
MR. KUNTZ: Objection.
A I wouldn't say it that way. I would say in SEM, we are looking at specific locations. We can't sample the entire mesh area. So it's -- we're evaluating. We haven't decided yet what to do with it.
BY MR. SNELL:
Q Is it fair to say as you sit here today, you have not decided whether or not to do statistically significant calculations upon the SEM testing part of the test?
A That's right.
Q For the XPS portion of this test, have you attempted to do any statistical significance calculations?
A Not yet. XPS is similar to SEM, in that we're limited to a relatively small area on the surface of the mesh, so we have a similar sampling concern. So we haven't yet decided -- with XPS we were more interested in

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confirming the existence of those carbon-oxygen bonds.
XPS is a useful technique for showing that the carbon is, in fact, chemically bound to the oxygen. And so we use XPS as a method to support the FTIR findings.
Q But to date, no statistical significance testing has been done on the XPS portion; is that right?
A It has not been done.
Q Did you attempt to analyze molecular weight in this test?
A We did not.
Q Why not?
A Molecular weight measurements require a considerable amount of material. Molecular weight measurements also aren't as -- with molecular weight, we are sampling the entire fiber. Whereas with these other methods, it's more the surface of the fiber. So it takes a lot of material, and it's difficult to isolate the effects of what's happening on the surface. In other words, it would take a lot of material to do that, and we didn't have that much.

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Q Well, you had a whole sling, correct?
A Yes.
Q That's enough to do molecular weight testing on, correct?
A It's difficult for us because we have to send these samples off to an external laboratory that requires a rather large sample size. And we would also want to analyze the molecular weight of that outside degrade and surface layer would be the most informative. So then the material requirements for doing that testing are pretty limiting, so we didn't do it.
We believed that the FTIR and the SEM would provide similar information about the breakdown in the structure at the surface. And FTIR and SEM are commonly used by many investigators in these types of studies. So that's why we did the study the way that we did.
Q Is it correct or not that you had enough material, considering you had a whole sling, to look at the molecular weight?
MR. KUNTZ: Objection.
A I don't know that we did, because we would

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have required separate replicates for that. And Dr. Dunn can speak to this better than I can, but there is not a lot of polymer in that -- I mean, it's a mesh. And so we needed to have separate replicates for the GPC. And we would have to have rather large samples in order to send them off for molecular weight analysis because we can't do it at Vanderbilt. We don't have the equipment.
So it would have taken considerably more material, and I don't know that we had it. But, again, Dr. Dunn can speak to that.
BY MR. SNELL:
Q Do you know if Dr. Dunn has done molecular weight GPC testing on other mesh manufacturers' slings?
A He has done some testing on exemplars in the past. But, again, my recollection of this is we had to send away a fairly significant amount of material. This is what I remember. Again, Dr. Dunn would be able to address that better.
Q Did you discuss doing GPC molecular weight testing and decided not to do it or is this a

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test that just did not really enter into your mind?
A Oh, we discussed it. We certainly discussed it. Our conclusion was with the amount of material that we had and the amount of time that we had, it made the most sense to focus on FTIR and SEM for this round of testing and XPS. We could do those tests with a single set of replicates and save those samples.
Keep in mind too, I don't think I was very clear on this point. But when I say zero, one, two, three, four, five, that's separate materials for each time point multiplied by three or four replicates for each time point, so you can see this is getting to be a rather large number of mesh particles.
Considering the time constraints we had, and the amount of material we had, we considered many different types of testing, XPS, DSC, all of this different testing that has been reported in the literature. We decided to focus on those three to answer the specific question of can it oxidize. FTIR

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and XPS, we believe were probably the best choices for answering that question of can it oxidize because they're chemical analyses. That was the rationale for why we did it.
Q This medium that you put the samples into which you believe mimics what a macrophage can produce in the body, what specific compounds or chemicals of the macrophage does this compound consist of?
A I think I know what you mean. So the chemical reaction, cobalt chloride reacts with hydrogen peroxide. Again, hydrogen peroxide is a substrate for this enzyme, myeloperoxidase or MPO in the inflammatory cells. That chemical reaction produces hydroxl radicals, OH radical. And those hydroxl radicals are the species that attack the polypropylene as we've discussed previously.
So it generates those hydroxl radicals, which are a form of reactive oxygen species in the body. Instead of generating this reactive oxygen species through a myeloperoxidase catalyzed reaction in a cell, we are doing this reaction in vitro by

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different reaction mechanism. But the end product is the same, these hydroxl radicals.
Q I think you said that you are doing this in vitro. That's not correct, is it?
A Doing what in vitro?
Q Let me back up. I heard you say something that just threw me off there.
A Okay.
Q When you put the TVT in this other control -- can I call it a solution?
A Yes.
Q Is there a specific common name that I can use?
A We can call it oxidative solution if you like.
Q I don't like that.
A You don't like that. Of course, you don't like that, do you?
Q Try again.
MR. BOWMAN: I've got a suggestion.
MR. SNELL: What?
MR. BOWMAN: The Anderson solution.
THE WITNESS: We can call it the

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solution, that's fine.
BY MR. SNELL:
Q Let's get really simple, though. Just so I understand, that solution, what is it made of?
A Okay. I can explain -- and, again, this is in the documents, but we mix a solution of cobalt chloride.
Q Okay. So that's a molecule of cobalt bound with chloride?
A I believe it's COCL2. Is it CL2 or CL3? I can't -- it's cobalt chloride. It's either COCL2 or CL3. I just don't have it memorized. But cobalt chloride reacts with hydrogen peroxide, H202. So the solution is 20 percent H202, hydrogen peroxide. I don't remember the concentration of cobalt chloride, but it's again in the SOP.
We mix those together, and they react to give reaction products, including hydroxl anion, that's OH minus. That's a basic solution. Plus OH radical, that's OH dot, so hydroxl radical. And then there is a valence change on the cobalt. I can't remember the changes it's valenced.

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But the main reaction product is that hydroxl radical that's simulating the reactive oxygen species formed by these inflammatory cells in vivo.
Q Okay. So the hydroxl radical simulates the reactive oxygen species from the macrophages in foreign body giant cells?
A It is. So the foreign body giant cells and macrophages produce a number of reactive oxygen species, and hydroxl radicals are one of them. So in the in vitro test, we are producing those hydroxl radicals and the Bonferroni ROS species produced by the inflammatory cells in vivo or in vitro. They do this in vitro as well.
Q How do you know that macrophages in foreign giant body cells produce hydroxl radicals in any particular case?
A It's been published in the Dr. Anderson papers that I mentioned that when these inflammatory cells adhere to the biomaterial surface, they secrete a number of these reactive oxygen species, including the hydroxl radicals.
Q How much hydroxl radical do they produce?

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A I don't know that anybody has measured that.
Q How much hydroxl radical is produced in this test that mesh was put into?
A We don't know. But the reason we ran the polypropylene control, I can try to answer that. So we know from Liebert, Liebert took the monofilament, the unstabilized polypropylene, and planted it subcutaneously in a hamster, and he saw a chemical induction. He saw oxidation induction of this oxidation reaction at 108 days. Okay.
So in our study -- that is 108 days to induction. That is in vivo in that hamster model, in vivo in the hamster model. In our study, we saw induction between days 21 and 28 for unstabilized polypropylene control. So if you average that, just to give you an approximation to try to answer your question, somewhere between 21 and 28 -- let's call that 25 days, and Liebert saw induction in vivo at around 100 days.
That tells us that events are happening in our in vitro test about four times faster than they happen in that in vivo hamster model, which is a subcutaneous suture

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implanted subcutaneously. That was -- the purpose of that control was to give us some idea of the relative time scale to relate our tests to in vivo conditions as an approximation.
Q In vivo in a hamster, though, not a person?
A Yes, in vivo in a hamster in a subcutaneous space, not the pelvic -- it could be much faster in a pelvic floor. But it was a suture implanted subcutaneously is what Liebert did.
Q What is the rate of induction of Prolene polypropylene in the pelvic floor?
A We cannot determine that from this test. There are many factors that affect that.
Q Is it correct that you do not know how much of the hydroxl radical is produced in the solution used by Dr. Dunn?
A I'm not sure if that's known how -- no, I don't know that we know that, but --
Q Well, let's see if we can do this. It would seem to me to be common sense that the amount of hydroxl radicals that would be produced in vivo would be somewhat dependent upon the number of macrophages; is that correct?

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A That would be one factor. The extent of the inflammatory reaction would be one factor that would affect induction time.
Q So if there were 1,000 macrophages present, the ability of hydroxl radicals to be produced quantity-wise would be much greater than if only ten macrophages were present. Is that a fair scientific statement?
A You're saying that you would expect more ROS with more macrophages? Is that what you're saying?
Q No.
A Okay. Say it again. I didn't get it.
Q The potential amount of hydroxl radicals that could be produced would be higher if there were 1,000 macrophages present as opposed to only ten. Is that a fair scientific statement?
A Present on like the --
Q Present at the mesh, present at the tissues.
A Per area of something like this, right?
Q Per the same area?
A Yeah. I mean, I think this is equivalent to what I said. If you have more macrophages per area, more foreign body giant cells, that

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is a factor. I mean, certainly that's a factor.
But, again, I want to emphasize that the point of the tests was not to calculate the rate of -- at which through the time at which induction happens. It was just to answer this question, can it oxidize, can it become induced, can it degrade. That was the purpose of the tests.
So we were not trying to say use these data to calculate the induction time of Prolene mesh in the vaginal space. There were a number of factors affecting this. All this test shows is that it happens. It can oxidize and degrade. That was the purpose.
Q What is the size of the solution that you put the single TVT device in?
A These were vials. I don't know. Maybe 20 milliliter vials. I can't remember the size of them. They were maybe that tall and maybe that big around (indicating). They were vials.
Q So you put a piece of the mesh in the vial, and the vial had the solution?
A Yes.

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Q Were all of the vials filled with the same amount of solution?
A Yes. I believe those -- I can't remember the number, but Dr. Dunn controlled for that.
Q As you sit here, do you know how much solution was put in each bottle?
A I don't remember the number. It was in the range of tens of milliliters. It wasn't more than 100. I don't remember the number. Dr. Dunn would know.
MR. KUNTZ: Can we take a break? We've been going for one hour and 45 minutes, almost two hours.
MR. SNELL: Yeah.
BY MR. SNELL:
Q One other question while we are taking about these vials and solutions. How many macrophages does one vial equate to?
A I don't know the answer to that. The best way I can answer this -- and I want to be responsive. But the best way I can answer this is compared to Liebert, we are seeing an acceleration of about a factor of four. Could that mean that there is four times as many -- it could, but it could mean other

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things as well.
I would rather say that there is lots of factors that can affect this. And it's basically accelerated by -- it happens about four times faster than what Liebert observed in that hamster model. I can say that. But how many macrophages, I -- we don't know how many macrophages Liebert observed. So it's very difficult to calibrate it to that level of detail.
Does that make --
Q I guess maybe if I can back up and just make this question as simple as possible.
A Okay. Yeah.
Q Are there any documents that are in those test files that say for this solution, for a given amount of the solution, that is the equivalent to the hydroxl radicals that can be produced by Y number of macrophages?
A I don't know that that correlation exists. I don't know.
MR. SNELL: Okay. Let's take a break.
(A brief recess is taken from 3:25 to 3:45 p.m.)

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(Deposition Exhibit No. 3 is marked for identification.)
BY MR. SNELL:
Q Dr. Guelcher, we are back on the record. We have marked as Exhibit 3, the thumb drive, that has the different documents, reliance materials, etc., that you brought to the deposition, correct?
A That's correct.
Q And what we're doing now, we are looking under -- there is a folder called Guelcher Reliance Docs that we're going to look under. And we are going to look for test materials, correct?
A That's correct.
Q And then under that there is a subfolder called In Vitro Testing. Is that a folder that you're looking at?
A Yes, I believe there is a folder called in vitro testing.
Q And the in vitro testing folder has test information pertaining to this test that you testified about earlier where Dr. Dunn conducted the test on the single TVT retropubic device compared to the

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polypropylene pellet?
A That's correct.
Q Now, within that in vitro testing folder, there are additional subfolders, correct?
A That's correct.
Q All right. So where is the study protocol?
A Okay. I'm going to have to look for that.
MR. KUNTZ: Again, there is a folder called protocols.
MR. SNELL: I hear you. I just want the witness to tell me that it's actually in there and show me where it is.
A I'm looking. Okay. Study design and protocols. There is a folder called study design and protocols.
BY MR. SNELL:
Q Okay. Give me a second. I'm in the study design and protocols folder. And where is the study protocol?
A Okay. There is -- I believe it's the oxidative media Preparation file. Let me look at that and I believe that is it. So that is what I was calling the SOP. It says, Guelcher labs standard operating procedure oxidative media preparation. This is how we

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prepared the medium that you were asking me about.
So it has the recipe for -- it's CoCL2, cobalt chloride hexahydrate, 30-percent hydrogen peroxide solution and water. And these materials are mixed to make the 1 liter master batch, and the procedures are all listed here for that. That is how we get the solution.
Q And how much is put into each of the vials?
A I will have to look at a different procedure, because I think this is just the master batch. Let me find it.
Q Before you leave that document, at the bottom left it says, ADT dash last edit 9/15/14?
A Yes.
Q Who is ADT?
A That's my graduate student, Anne Talley. She is the one who has been maintaining this draft that I have approved.
You asked about what, how much is added, the volume?
Q Yes, the volume added to the vial of the solution.
A Okay. I am going to have to go back and look

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for that.
Okay. So I found it. I believe the file is called in vitro mesh testing sample ID's. There is an Excel file in that same folder that we were talking about.
Q Okay.
A And you can see that all of the sample numbers are listed here. And if you scroll to the bottom of that spreadsheet, you will see procedure. And so if you look on the procedure, line number five, place 5 milliliters of oxidative media in each file. So that would be -- and then he has notes on what he did. So it's 5 mils, approximately 5 milliliters of the media, of solution, in each file.
Q In Anderson's paper, did he use 5 milliliters of solution?
A I don't remember the number that he used or that I used in my papers. I don't remember that number.
Q Do you know if you deviated from the amount that Anderson used in this test?
A I don't know. I'd have to check it.
Q Did Dr. Dunn decide the procedure to use

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approximately 5 milliliters of oxidated media in each file?
A I don't know that the Anderson paper specified this level of detail. We did discuss this. The Anderson paper did not present a procedure in this level of detail that I remember, but I would have to confirm that by looking at the paper. Do you want me to do that?
Q Who was it who decided to use 5 milliliters of oxidated media in each file?
A I don't remember. We discussed this test. I don't remember discussing where exactly that came from. I know -- I'm trying to find this.
Okay. Is there a question? What was the question? I don't remember. I thought I answered it, but I will answer it again.
Q Let me just ask the question again. Who decided to use approximately 5 milliliters s of oxidated media to be put in into each vial?
A I know we discussed this, but I don't remember the details. We discussed all of these points, and I just don't remember that,

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any more details than that.
Q The same number of samples of unstabilized polypropylene control were not used as the TVT; is that correct?
A I need to look at the spreadsheet again. Polypropylene standard -- you say the same -- why -- I don't see that. Where are you looking?
Q I'm looking at the Excel file you pointed out at above PP standard. Let's just make sure. Is the PP standard, is that the unstabilized polypropylene control?
A Yes. And to get back to one of your previous questions, the MSDS and the supplier for that material is here.
Q And so for the unstabilized polypropylene control, there were only 15 samples, correct?
A Oh, I see the top of the column, 15 samples. That's probably because it became oxidized more quickly. I don't -- so we only went out to four weeks with the -- because it became induced faster, the 15 samples. I don't know the answer to that now, what the number of replicates for each time point was. I can't tell from this table.

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Q Why were there only 15 samples of the unstabilized polypropylene control, but 36 samples of the TVT?
A Well, one reason would be because we didn't do as many time points. We did four weeks, it looks like, instead of -- and I don't think that we did as much -- I spoke incorrectly. I think previously it appears that we actually had separate samples for XPS and FTIR, and it doesn't look like we had as many XPS samples. I would have to think about that.
Q Do you know why you only analyzed the unstabilized polypropylene control out to four weeks, whereas you analyzed the TVT later?
A It became induced faster, so the unstabilized control became induced between weeks three and four. So we didn't do as many time limits.
Q You could have still tested it, though, at five and six weeks, right?
A We could have.
Q Did you make an affirmative decision not to test at four and five weeks or is that

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something that Dr. Dunn did?
A I can't remember the details of that decision right now.
Q Who made the decision to only use 15 samples of the unstabilized polypropylene but 36 samples of the TVT?
A I don't remember those details either.
Q When you do statistical analyses comparing the unstabilized polypropylene to the TVT, don't you have to take into account differences in sample sizes and differences in the quantity of time points analyzed?
A Yeah, for comparing between -- for comparing between groups, those factors would have to be taken into account, but I just don't remember the details of that study design.
Q Who did the FTIR testing?
A Dr. Dunn.
Q He personally did it or did he have somebody else do it?
A I believe he did it. But, again, it was done through his company, so I don't know the details of who actually did what measurements, but I believe he did it.
Q Do you know where this FTIR machine was that

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was used in this test?
A Yes. It's in his laboratory.
Q So he used the Vanderbilt lab FTIR machine for the test?
A Well, I would say he used the FTIR in his laboratory at Vanderbilt.
Q Did he buy that FTIR machine?
A He would have to speak to the details of that.
Q I guess the question is -- you took issue with whether I asked you -- do you know who owns that FTIR machine? Is it Vanderbilt or Dr. Dunn or --
A I don't know the details of that. When you said the Vanderbilt lab, that was, I thought, a little vague. I wanted to clarify that it was -- it's in his laboratory space that he has been assigned at Vanderbilt.
Q Okay.
A That's what I meant.
Q All right. But it very well could be that that is a machine that is actually owned by Vanderbilt?
A I don't know the details. As I said, Dr. Dunn has an agreement with the

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university. That's all I know. He would have to speak as to the rest of it.
Q Now, the SEM analysis, whose SEM machine was used?
A There is an SEM instrument and it's an institutional resource. It's a shared resource is perhaps a better way of saying it, and so we pay for machine time.
Q Is it located at Vanderbilt?
A It is.
Q In what school?
A Well, it's an institute, so it's between schools and the members of the school of engineering, college of arts and science, medicine. It's a shared resource.
Q It's not in Dr. Dunn's lab?
A No.
Q Physically where is it? Is it within a building in the department of medicine? Department of engineering?
A Again, it's a building that has shared space between the college of arts and science and the school of engineering.
Q Who did the SEM images?
A Again, it was Dr. Dunn's company. Whether he

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had an employee doing that, I don't know. He was responsible for all of that.
Q The XPS machine that was used to look at the sample, where is that machine?
A So that machine is also administered by the institute I was referring to earlier. It's housed in the laboratory of Professor Bridget Rogers. So to clarify just for the record one of the earlier questions about who else at Vanderbilt was involved, Professor Bridget Rogers is a professor, an associate professor of chemical and biomolecular engineering, and she did the XPS testing.
That slipped my mind earlier, I'm sorry, until we talked about it now.
Q So Dr. Rogers was actually the one who did the XPS testing on this single TVT retropubic device and the unstabilized polypropylene control?
A She did.
Q Were you there when she did the testing?
A No, but I don't need to be there when she -- it's a -- she ran it and --
Q Why didn't you do the XPS testing?
A That's Dr. Rogers' particular area of

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expertise. She has a lot of experience with it.
Q Is Dr. Rogers an expert for plaintiffs in transvaginal mesh litigation that you're aware of?
A Not to my knowledge. She was contracted by Dr. Dunn to do the work.
Q Do you know how much she was paid by Dr. Dunn?
A I don't know the details of that. Probably the same as my arrangement, but I don't know.
Q Was she aware of Dr. Dunn's role as an expert in transvaginal mesh litigation?
A Yes, she was, to my knowledge.
Q She is aware that Dr. Dunn is being paid by attorneys for plaintiffs in transvaginal mesh litigation?
A I believe she would.
Q So when she sat down to do this XPS analysis, she knew that the money was coming from plaintiffs' lawyers in transvaginal mesh litigation?
A Yes, I believe she knew that. I haven't -- I'm hesitating because I can't remember explicitly discussing that with her, but I

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believe based on conversations with Russell that she knew she was being paid by litigation.
Q Did Dr. Dunn have a conversation with Dr. Rogers about doing this XPS testing?
A Yes.
Q Were you present at the time of that conversation?
A For some of the conversations, we did discuss it as a group with Professor Rogers. Was I there for every conversation, I can't say that I was. I did discuss this with Professors Dunn and Rogers.
Q And what was said?
A Well, we discussed how to do the analysis, what we were looking for, how we wanted to do the experiment, and what the goal was. We discussed the approach for the measurements.
Q Who paid for the SEM time?
A Again, I can't answer that -- oh, for the SEM. I'm sorry. I believe that Dr. Dunn has a sponsor research agreement through the university in which he set up a cost center. But, again, he has to speak to all of this. I believe it was paid for by the litigation

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through a center number from the university.
Q What do you mean by center number?
A Well, when we do internal billing within the university, we have cost centers associated with different funding sources. So he would have used the cost center associated with his sponsored research agreement. But, again, I am hesitant to go -- it's his project. I don't know the details of that.
Q Who paid Dr. Rogers for her time?
A Dr. Dunn. She invoiced Dr. Dunn, and then Dr. Dunn invoiced plaintiff's counsel.
Q How much did Dr. Rogers' invoice in connection with this test that you're relying on?
A I don't know the answer to that.
Q Do you know how much Dr. Dunn has invoiced in connection with this test that you're relying on?
A I haven't seen his invoices. I don't know.
Q Would it be based on your understanding more than $50,000 as an accurate prediction?
A I don't know. I can't put a number on it because I didn't see the invoices.
Q For the use of the XPS machine, am I correct

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that someone would have to pay for that time or usage as well?
A I don't know the details of that arrangement with the XPS with Dr. Rogers. I can't speak to that.
Q The unstabilized polypropylene control, is that contained within the file that says polypropylene standard MSDS?
A You were interested about the source?
Q Yes.
A Yes, I believe that it is, and I'm going to look at it right now. So this is the file, polypropylene standard MSDS, and I'm clicking on this link.
Okay. This is an MSDS. I believe it is the polypropylene standard. If you see the ingredient, it says isotactic polypropylene at 100 percent. So this would be the unstabilized polypropylene control. It was purchased from Scientific Polymer Products, Incorporated, and that would be the MSDS for that material.
Q And this is the pellets that you were talking about?
A Yes.

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Q These aren't the same pellets that are used in the TVT device, correct?
A Not to my knowledge.
Q What is isotactic polypropylene?
A That is just a reference to the structure of the polypropylene. Most polypropylene is sold commercially. And my understanding is isotactic is the most common isomer. I will say to my knowledge that polypropylene used to make Prolene is also isotactic, if that helps.
Q Are you certain of that?
A Pretty certain. I believe that's the case.
Q Section 9 has different physical and chemical properties of this unstabilized polypropylene control?
A Section 9, yes.
Q Do you know if these properties are in any way different than the polypropylene pellets that are used in the TVT device?
A Could you ask that again? I didn't catch it.
Q Sure.
For the chemical and physical properties of the unstabilized polypropylene control that you used, are you aware if the

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properties are any different than the same properties for the pellets that are specifically used in the TVT device?
A These properties appear to me to be very similar. If I'm looking at Sections 9 and 10, the melting point of 160 degrees. This is the melting point I remember for Prolene from some of the internal documents, the saline water is negligible.
If we look at stability and reactivity, it also says materials to avoid, oxidizing materials. It looks very much like something I would see for the MSDS for the polypropylene used to make Prolene that I saw. So to answer to your question, I would say it looks similar to me.
Q And for the SEM test results that you --
A Did you open the file? Is that where you are?
Q Yeah, I was going to ask you. The SEM test results you believe showed pitting and you said peeling. Would those be found in that folder PCT-168SEM?
A I'm looking. SEM, yes.
Did you have a question or --

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Q I am just trying to see, are the SEM images that you referenced in that file PCT-168SEM?
A I'm looking at a file TVT five week SEM PDF. I'm not sure what you're asking me. If you can just ask me again what you're looking for.
Q The particular SEM images that you referenced that you be believed showed pitting or the peeling?
A Yes.
MR. KUNTZ: I will object. But go ahead.
A Okay. So I'm looking at this. I'm in this SEM directory. I'm clicking On TVT five weeks. There is a folder called TVT five weeks, and I believe these are individual files. And then I believe this file TVT SEM, TVT five weeks SEM PDF, I believe that that is the file I was talking about earlier.
So when I open this file, I see a number of SEM images of PET that show that there is a pitting and flaking on the surface of the TVT. That's what I was describing earlier.
BY MR. SNELL:
Q On the second photo -- can you look at my

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computer?
A The second photo is called PCT168SEM007.
Q Yes, that's what I'm looking at.
A Okay.
Q And towards the middle, that's a fiber that we're looking at?
A Yes, that's a specific fiber.
Q Take a look towards the middle at the bottom, if you can look at what I'm looking at. Right here.
A Yes.
Q Right above the times 400.
A Yes.
Q And then moving directly north in the middle here. What is that?
A That looks to me like an area that I would call degradation, where the surface is changing. It looks like there is some pitting and some residue, blistering perhaps. That looks like an area of surface degradation.
Q In the SEM photos that I've seen in the literature, those typically show cracks running horizontal, correct?
A That's right.

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Q This does not show anything like that, correct?
A We don't see the cracking because we did not apply -- these materials are not under tension. There is no residual strain. So in the Anderson paper 1993, they prestressed the materials. And when they did this -- and they incubated them in an oxidative medium. When they did this, they were able to see environmental stress cracking.
We did not prestress the materials. Again, the question was really to answer can it oxidize. So without that mechanical stress, we see more of these effects of peeling and blistering. And this is described in a number of papers to see environmental stress cracking you need a combination of three things. One is an oxidative medium, the second is a material that degrades in response to that medium, and the third is mechanical stress.
So that -- there is no mechanical stress in this experiment, which would be why I don't believe we were seeing the transverse cracking as noticed in Clave and other

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papers.
Q Isn't another just as plausible answer that there is no proteins and biofilm on these images?
A Not in my opinion.
Q Let me ask you, were proteins and biofilm actually put on your samples of the TVT device?
A So I want to be specific about this term biofilm. Biofilm is a polysaccharide matrix. It's deposited by bacteria. To me that's different than protein absorption. And I'm not aware of papers that are saying protein absorption is causing cracking. I mean, but the biofilm to me is the polysaccharide matrix deposited by bacteria.
Protein absorption is something different, but it -- I mean, the surface is degrading here is what I see in response to the chemical induction is how I interpret these events.
Q There is no cracking in your photos of the SEMs similar to those seen in the body as in Clave and Costello and de Tayrac, correct?
A Again, there is no cracking here because

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these materials were not under any mechanical stress. There was no force. They weren't pre-strained like in the '93 Anderson paper. This is a protocol that was used in the '97 Anderson paper to answer the question of oxidation. We didn't have mechanical strengths, and that's why we're not seeing cracking.

Q You would agree that another plausible explanation for why you don't see cracking is there was no biofilm used in your testing?

MR. KUNTZ: Objection.

A I don't agree with that.

BY MR. SNELL:

Q Have you seen anywhere in the literature during your analyses where cracking was seen on an explant, and upon cleaning the explant, it was determined that biofilm was the source of the cracking? First of all, have you seen that in the literature?

MR. KUNTZ: Objection. Go ahead.

A I believe the paper you're talking about that I've seen was -- and correct me if I'm describing the wrong paper, but I have seen a

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paper where the mesh was challenged with bacteria. We have a contaminated mesh. And then the SEM images I saw -- this is only 30 days, and this SEM image showed what appeared to be a biofilm, which I would expect, because it was challenged with bacteria, and that biofilm showed cracks. But it looked like a biofilm. It didn't look like the SEM images in Clave. And some of the other explanted mesh papers don't look like biofilms to me.

We can look at that paper. It's in my reliance materials. I can look for it, but I believe that's the paper you're referring to, and I have considered that. I believe that's a biofilm. And if you wash that biofilm off, it goes away, and there is no damage to underlying substrate, because it's only 30 days. And so these events may not have started happening yet, because 30 days is a relative short period of time. That's my explanation of the paper that I believe you're referring to.

Q It's the de Tayrac paper. You're aware of that? There is actually images where they

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show the cracks. And then after they have cleaned off the biofilm, you know, it was clear that the filaments were fine?

A Yes, but I think this is a different question. I agree with what that paper is saying in that -- we can pull it up and look at it again. I'm going on my memory, but I think it was only 30 days. And I have done these experiments myself. I've contaminated scaffolds and placed them in -- I just published a paper on this last year -- we placed it in a bone defect.

We come back four weeks later, and we see a biofilm, and it looks a lot like that biofilm. And they clean it off, and, yeah, there is no damage to the polypropylene because it was only 30 days. It was a very short period of time. And as we've been discussing from Liebert and some of these other papers, we wouldn't -- scientifically, polypropylene would be induced at around 100 days.

So it's not too surprising to me that in 30 days, the polypropylene hasn't started to crack yet. That's a very early time point.

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That's the way I understand that paper. But, again, I would be happy talk about it with you, but that's my memory of that paper.

Q Do we know how much the Prolene polypropylene is induced at 120 days?

A I think I know what you're getting at, but I would like you to ask it a different way. Induction time, it's an event, so we can't say how much it's induced. We can say either it's become induced or it has not. So are you asking -- I guess I'm not sure what you're asking.

Q What is the significance of induction?

A So it's described in many of my reliance materials. But an induction -- just to think of a plot, we see a small change in properties. So it's oxidizing, because there is adherent macrophages in giant cells, and it's oxidizing.

And then we reach this point where the reaction becomes autocatalytic, and there is a very strong increase in the slope, kind of like hockey-stick applied. And that change in the slope, we refer to as the chemical induction time. So it's an event.

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So to say how much it is induced, I'm -- I'm trying to explain why I can't answer that question.
Q When does that chemical induction time take place with the Prolene polypropylene?
A We talked about this earlier. It's difficult to -- when that happens in the body is going to be affected by a number of factors. But it's -- I think it's unlikely that that would happen in 30 days. That's very early. And that's why I explained the biofilm -- it could happen maybe in some conditions in 30 days, but I don't believe in that experiment.
Q Is there a certain point in which it becomes significant?
A What becomes significant?
Q This induction.
A Well, it's an event. So at induction, there is dramatic changes in physical properties. But embrittlement in these events can happen even before induction. But, again, that experiment is just -- they have this one -- it only went out to 30 days, and I just don't think they went far enough to see the stress cracking.

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Q I'm looking here, and there is a folder called TVT six week SEM?
A Yes.
Q That would be the six-week images?
A Let me open that. Let me pull it up. I think that is what it is, but -- yes, that would be the six-week images.
Q Why were SEMs only done on some of the samples?
A We were limited by the number of samples and just the amount of time to get this work done. And so we know that, as I was just explaining, once we reach the induction time, that we would expect to see these significant physical changes, physical degradation.
And when the FTIR measurements told us that it was induced between weeks four and five, we did SEM images at week five, and then compared to the pristine sample, because we were comparing the period in which it's become induced. We still have the samples, I believe.
And I think we did this really out of time constraints because there was so many samples.

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Q Under PCT 168 XPS --
A Oh, you're on the XPS now.
Q I'm in a Document 11062014 PCT 168 report.
A Are you looking at the XPS report?
Q Yes. This is actually from Bridget Rogers.
A Okay. I am pulling up the report.
Q On the second page, table one, it says fraction of carbon atoms bonded in the RCOOH and the CO configuration?
A Right.
Q What is that RCOOH?
A So RCOOH is the hydroperoxide group that's formed when the polypropylene is oxidized. It's an intermediate in that complex reaction mechanism.
Q And what does it mean when there is zeros in this table?
A So if it's a zero, that means that in that particular spot she was looking at under the microscope, there was no oxidized polypropylene. In that particular spot, the polypropylene had not been oxidized. And then where we see the numbers is where we see evidence of oxidation of the polypropylene.
Q What does the C equal sign --

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A That's a carbonyl bond. That's also a reaction product.
Q Why is there supposedly a carbonyl bond in sample two in one week?
A I'm not sure.
Q That makes no sense base on the literature and data as you understand it, correct?
A I wouldn't say it makes no sense. I mean, it could be that small regions of the polypropylene are oxidized before they were implanted. We have seen that in other exemplars. It is possible that there is oxidation on the mesh before it's even implanted
Q Where would that oxidation come from on the mesh?
A Thermal processing. When it's extruded and processed at high temperatures, if those antioxidants get depleted, it's not surprising to me that you would see regions -- we have seen it on exemplars. And I can't say which meshes, but it's possible for the mesh to be oxidized during processing.
Q Is it your opinion that this shows the TVT mesh is thermally oxidized?

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A That's not what I'm saying. I'm saying that that could be an explanation for why that number is not zero.
Q Another explanation could be that her test is just wrong, correct?
MR. KUNTZ: Objection.
A I wouldn't say it's just wrong. I would say that when you look at the XPS as a whole, it's consistent with the FTIR data. We see regions of oxidation, and those numbers generally increase with time. And that point at one week -- yeah, there could be multiple explanations for that.
BY MR. SNELL:
Q You would not expect to see a reading at one week for the CO bond, correct?
A No, not if -- I mean, if it had regions of oxidation, that could happen. It could have been that in that particular measurement, she was looking at a region that hadn't been oxidized during processing. That can't be ruled out.
Q Well, what are all the possible reasons why you could find this CO finding in the second TVT sample at week one, besides there could

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be thermal oxidation that you're saying, I guess?
Could her equipment not be calibrated or running properly on that certain day?
A I think that is pretty unlikely. I think that it could be that there was a region in the mesh where the antioxidants had been depleted and oxidized very quickly. It could have happened during thermal oxidation. I mean, those are some examples of what could have happened.
But I don't think one data point that is somewhat unexpected can be used to support the notion that the method is flawed. You can't rule out that the polypropylene wasn't oxidized. You simply can't really explain that data point. There is several possible reasons, and none of them is terribly conclusive.
Q Did you ask her why in the world, Doctor, are you showing a positive finding in one week in the CO bond in the second sample?
A We discussed it with her.
Q But what did she say about why that finding was there at one week?

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A She said that's what she saw. She trusts her methods. She stands by her methods. I'm not shocked, because as I said, we have sufficient oxidation in these meshes. The exemplars, you open them out of the box, and in some cases, we have seen oxidation. So I'm not shocked by this.
Q Is it correct that one explanation could be that something was wrong with her equipment on that date, with the calibration or the test methods she did on that particular sample?
A It's a possibility, but an unlikely one.
Q Did you go back and look at any documents or any log books or anything like that with regard to what happened during that testing on week one?
A We looked at -- Dr. Dunn and I and Dr. Rogers reviewed a fair amount of the original data, which she showed us the peaks in the XPS spectra.
She has an algorithm for separating the peaks, as described in her report, and that's what she saw. And, again, this is looking through a microscope at one small spot on the

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surface, and she saw this region where there was some evidence of oxidation.
Q How small of a spot was that?
A I don't know the size of the spot, but I know that she does this through a microscope.
Q Do you have an idea or a range? I mean, are we talking about couple of microns or 1,000 microns?
A It's not -- you know, 1,000 microns would be a millimeter. It's not that big. I don't know the exact size of the spot.
Q There were no positive findings at week two, correct?
A When you say positive, there was no evidence -- none of the spots she looked at at week two showed evidence of oxidation. That's the way I would describe that.
Q And how do you explain that?
A Well, because she didn't see any evidence of carbon-oxygen bonds at week two on any of the spots she looked at.
Q On week three, there were only two findings that were positive, correct?
A On week three, there were two spots where she saw evidence of oxidation.

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Q On week three, second sample, it says 0.0088. What does that mean?
A Let me look at her report in a little more detail and make sure I answer that correctly.
So table one presents the fraction of carbon atoms bonded in the RCOOH and RCO configurations. So that would be -- the fraction of carbon atoms for that would be 88 percent of the carbon atoms would bond to that group is what she is reporting.
Q At week four, there was only one positive finding, correct?
A Again, there was one spot that showed evidence of oxidation.
Q Do you know why she didn't have a positive finding in the second and third samples, but had one the week before supposedly?
A I wouldn't say supposedly. Again, we are looking at individual spots. And if you look at the SEM images, you can see that there are regions where there is degradation and then regions where there is not. So there are regions on the surface of this polypropylene that are oxidized, and there are regions that are not. And this is -- these are the number

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of areas that that is what she observed.
Q You said you all looked at the raw data where there were these peaks and things like that. Where is that in this production?
A I don't see that in her report. We have that data. I'm not sure where they are.
Q I'm going to request those.
A Yeah, and that's not going to be a difficult thing to provide.
Q Has she done any statistical testing on that XPS?
A No. And as I mentioned before, XPS is really a qualitative tool to assess the structure of the bonds. It's telling us that we see these carbon-oxygen bonds that are indicative of degradation. It is confirming the FTIR findings. We are relying on the FTIR findings for a more quantitative analysis where we will run our statistical tests.
And it's because with XPS, we are looking at different spots, and we can't distinguish whether it's a degraded spot or whether it's a non-degraded spot. What the XPS data confirms is that there is regions of degradation, and we can even see evidence of

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induction at week five.
At week five, we see these remarkable -- we see two spots, where now we have essentially 50 percent of the carbon atoms which she was looking at that are bound to oxygen. We look at these data in week five. The first two samples -- in the first sample and the second sample, we see a dramatic increase in, so that's what --
Q In the third sample, there is no increase, right?
A That's a region where -- well, there is some carbonyl showing up, but that's a region that was less oxidized than the other two. That's the way I would interpret that.
Q The zero means no oxidation seen, correct?
A Well, I think we have to -- as Dr. Dunn has testified previously, we need to consider these two peaks together, because we are most entered in looking at the fraction of carbons that are bound to oxygen. That tells us about oxidation. So we do see some carbonyl. And there is no COOH group in that sample.
And, again, it is because we are looking at different -- it depends on the spot that

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you are looking at.
Q The CO, that's the carbon oxygen, the carbonyl?
A The CO is a carbonyl bond.
Q Right.
So in the first sample, there was no positive finding of the CO bond at weeks four, five or six, correct?
A That's what it says, right.
Q How do you explain that finding?
A Again, I would look at this as adding because these are -- you know, she is trying to separate these two peaks using a mathematical algorithm. And, you know, I think we have to consider both numbers when we talk about whether the surface is oxidized or not. Both of those types of bonds can occur on the surface. That is the way the test works.
Q Even though there were, as she supposedly records, RCOOH bonding, at weeks four, five and six, there is no CO bonding. That's fair, correct?
A That is what her analysis shows.
Q And there is zeros at even weeks five and

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six, correct?
A Again, it depends on the spot you're looking at.
Q Is it true or not, though, that there is zeros at weeks five and six?
A Yeah, that's what I just said.
Q And these numbers are not consistently showing oxidation across all samples at the same time point either; is that correct?
A That's correct. And, again, that's because of where you are looking, just like the SEM images, not all regions are degraded.
Q Or it could be because of issues in the test, correct?
A Unlikely.
Q But that's a possibility?
A It's always a possibility. I mean, it's a possibility of any test.
Q Have you done any analyses on cadaveric slings?
A No. Cadaveric slings in my understanding aren't made of out of polypropylene.
Q I think I would agree with that.
But my question is simple. Have you done any testing on cadaveric slings?

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A No. Why would I?
Q I'm just asking.
A Okay.
Q You're reading too much into my question.
A It's just this kind of came out of no where.
Q Have you ever done any testing on biologic slings?
MR. KUNTZ: Don't do this.
MR. SNELL: I'm going to come back to it, I'm sure.
BY MR. SNELL:
Q Are you aware that biologic slings can degrade?
A Okay. I would not use -- your terms are a little -- when you say biologic, are you talking about like the autograft or the allograft? What do you mean by biologic?
Q You know like a pig sling.
A You're supposed to call that a xenograft. I don't know that I would use the word degrade. I would prefer to use a word like remodel. It's reabsorbed, you know, so the old tissue in the xenograft is absorbed, and then new tissue is deposited by it. That's my understanding of what you're saying, I think.

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Q Have you ever investigated the biocompatibility of porcine slings?
A What do you mean by biocompatibility? That's a pretty controversial word. You mean in an ISO context or -- I'm not sure what you mean.
Q I thought somewhere you talk about biocompatibility.
A Where do I talk about biocompatibility? I want to be very careful with that word because it has a very evolving meaning. There is an ISO 10993 biocompatibility test that measures certain characteristics of the device. But biocompatibility really can be best understood in the context of the material and where it's being implanted. I'm not sure what you're asking about is the problem.
Q Have you done any analysis on cadaveric slings for incontinence? Meaning, have you searched the literature to try to understand whether they degrade, whether they remodel, anything like that?
A I have looked at that some, but not -- my understanding is that there is this Burch procedure where they can use autograft, I'm

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aware of that, where they harvest autograft, There is the Lynn paper that talks about harvesting autograft and then implanting that as a sling. I'm less familiar with the allograft and xenograft models. I don't know where you would get allograft for something like this.
But you're saying that there is a pig xenograft --
Q Sling.
A I'm not so familiar with that.
Q Okay. Have you have done any research or seen any literature that specifically looks at polypropylene slings and determines that they did not degrade?
A Again, I would like to be careful about this word degrade, so I'm going to answer your question as best as I can. I have seen papers that report findings that the sling does not degrade.
There is a paper by Professor Dmochowski at Vanderbilt, he is a co-author on this paper where they looked at -- but they didn't use the types of techniques we're talking about. My understanding of this paper is

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degradation was assessed by a pathologist from an H&E stained section. And it's not clear to me that you would be able to see degradation with a method like this unless it were really bad.

So I'm aware of those papers, and I have read them, and I have considered those views. My concern is that they don't always use these same techniques.

Q What doctor was that? Was that a doctor?
A Yes. He's a urologist at Vanderbilt.
Q Dmochowski?
A Dmochowski. That's who I'm talking about. And I think you know him.
Q Any other papers?
A That's the one that comes to mind. I think there are others too, but that is the one that comes to mind. I mean, there is these Nelson studies and these other papers, but, again, they're not specifically looking -- they may report that there is no degradation, but when you read the paper, it's -- well, in this case, they do patient surveys.

So how are you going to know that the mesh degraded if you're just talking to

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someone in a survey. So I'm aware that those papers are out there, and I have a read a number of them.

MR. SNELL: We are going to mark your summary of opinions as the next exhibit.

(Deposition Exhibit No. 4 was marked for identification.)

BY MR. SNELL:

Q So as we go through your opinions -- and just to perhaps save us a little time, these are the similar or the same opinions that you had at the Huskey case, correct?
A Yes, most of them are. If it would help, I can distinguish which opinions have been modified or are different since Huskey.
Q Yes, that would be great.

Let me ask you to look at the exhibit we marked for your summary of opinions in Mrs. Perry's case, and tell us if the opinions have been changed or added or modified as compared to your Huskey opinion.

A So I believe opinions one, and two, and three, four, five, those five opinions are very similar to Huskey. What I would say is new is the testing that we did further

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supports these opinions, but it doesn't change them.

So if we look at opinion three -- and we talked about this, but if we look at opinion three, the antioxidants do not eliminate degradation, and they do not guard indefinitely against oxidative -- this is -- the testing is relevant to this opinion. But other than that -- again, it's the same opinion. I'm just saying that the testing further supports it. It doesn't change the opinion.

Q The testing you're referring to is the testing that we've been looking at?
A That we've just discussed, yeah.
Q And that's pertinent to opinion number three about the antioxidants?
A I would say it's really pertinent to all five, but most specifically of opinion three I would say. Opinion six, I think, is similar. I did talk in Huskey about Ethicon's internal documents -- I'm referring to oxidative degradation.
Q Which document are you talking about there?
A There is the Guidon study, the eight-year

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explanted suture study. There is some other -- the dog study even shows evidence of degradation. Those are the two that come to mind.

There is some comments in those reports about scraping off material that appeared to be degraded polypropylene on the basis of its melting point and appearance, and environmental stress cracking in the sutures. All of that was discussed in Huskey.

Q In the Guidon eight-year explant suture study that you referenced, when did those findings of dyspareunia show?
A When did those findings of dyspareunia -- see that. You're being cheeky now.
Q Yeah.

In the Guidon finger explant suture, that's the vascular graft?

A That's right.
Q All right. At what point did the positive findings that you relied on show up on that study?
A So it was the eight-year time point where the surface cracking became -- I think there was some cracking observed at earlier time

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points, but in eight years, I remember it being very severe.
Q And the dog study, at what point in time did any of those findings become significant?
A I would have to look at the documents again, but my latest review of them, it was -- what I remember is the conclusion from the study is that the cracking became worse with time, up to seven years. Again, that was all discussed in Huskey.
Q I didn't see that. I don't know if you focused on the timing.
A Okay. Well, I just read this last night when I was preparing, and I remember some statements saying that the cracking appeared to get worse. We can pull it up if you want to talk about it.
Q Yes, let's just pull it up. I just want to understand what you're talking about.
It would be under reliance documents?
A I believe it would be.
Q Do you remember how you had it labeled?
MR. KUNTZ: Do you want to ask some questions about it?
MR. SNELL: Yes, just that one

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question about the time point.
MR. KUNTZ: You can use my copy, but I don't want it marked as an exhibit. It has highlights on it. I mean, just to speed things up.
MR. SNELL: That's fine.
(Off-the-record discussion.)
BY MR. SNELL:
Q Okay. Go ahead.
A I'm just going to give you some points here. So there is -- my understanding is that this dog study was designed to be a ten-year study. There was a five-year report that was issued. In five years, two out of the seven Prolene explants revealed cracking in five years. And then there is some SEM images here that show those explants, and I can see the cracking that they're referring to in two of those explants.
I would say that at least in the image I have it's difficult to tell, but it looks like there is a third one that might be showing some evidence as well. This is what I can see in these micrographs that are not terribly clear. That was the five-year time

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point. Now, I'm looking at the seven year time point. And the conclusions I am reading here, the seven-year in vivo results generally substantiated the five-year findings, degradation in Prolene is still increasing.
So the way I interpret this is from year five to year seven, the degradation is progressing, but I don't see any SEM images here.
Q Do you know from that study when the cracking first appeared, besides in five years?
A A few time points I have is five years and seven years is what's shown in this study. And then the fact that it got worse from year five to year seven, and that's what is reported in this study. And that's what I am relying on for this opinion.
Q That study doesn't establish that the cracking was there at, say, three years?
A It doesn't establish it was there at three years because there was no three-year time point.
Q All you know is that at five years, two out of the overall sample had some cracking?

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A That's right.
Q So you were looking at your list of opinions, and you had talked about number six. And number seven?
A So number seven, Ethicon ignored the warning contained in the MSDS for the polypropylene use in its products. It says the strong oxidizing agents, like peroxides, are incompatible with the polypropylene to the detriment of patients implanted with the mesh. So the MSDS warns that polypropylene is sensitive to oxidation.
Again, our testing plays into this because our testing has shown that even with the antioxidants, it can oxidize. They don't protect it forever, as I've wrote in opinion three. And this is a detriment to patients implanted with the mesh for two reasons.
One is, we've seen that oxidation degradation can lead to embrittlement, pain, and complications, as I have testified, with Costello and Clave and Huskey in previous testimony, and it increases the risk. It's unpredictable, so it increases the risk to the patients. It's a risk that they have to

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live with for their entire lives because the device is there.
And as long as it's there, it's going to be -- this reaction is ongoing. That's opinion five. And it's important that the antioxidants don't protect it forever.
Q That's basically the same as what you expressed in Huskey?
A I believe it is. I just wanted to qualify that I do believe that the testing data has some impact on that opinion, and we've been discussing that. But it's a similar opinion to that held in Huskey.
Q What about number eight?
A Number eight, I think, is also similar to Huskey.
Q In Huskey, as I recall it -- I mean, the primary studies and documents that you referred to and relied upon were the dog study, the vascular suture graft study, Clave, Costello?
A Yes.
Q The other one you mentioned today, Liebert, is that another one that is important to your opinions?

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A Yes, all of those studies that we've discussed.
Q Okay.
MR. KUNTZ: I'm just going to object. We have provided everything to you he has relied on. It's not a memory test to point out every single document, but I think I understand your question.
A I testified that on those at Huskey, and my opinion has not changed in that regard.
BY MR. SNELL:
Q And so I'm not going to recover those things with you.
A That would be great.
Q You're not offering any medical or clinical opinions with regard to Mrs. Perry at all; is that correct?
A That's correct.
Q That would be totally outside your expertise, correct?
A Medical and --
Q Clinical?
A Medical and clinical? Just for the record, I would not say it would be outside my expertise to test the explanted mesh and

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provide evidence of oxidation and degradation and conclude that that contributed to the embrittlement of the mesh. That could be done. I did not do that in this case. I didn't have the materials, but I don't want to -- I would say from -- I don't -- maybe to give you a better answer, I am not reviewing medical records and --
Q You're not doing a differential diagnoses and drawing causal relationship inferences?
A Not in this case, no.
Q Nor in general, correct?
A I have testified that -- again, I saw evidence of myeloperoxidase, which was evidenced to me that these oxidative processes are ongoing. That would lead to changes in the polypropylene. So in terms of -- you had a question?
Q The myeloperoxidase is not something you have done on an Ethicon mesh?
A That's correct.
Q It's not something you have done on an explant from an Ethicon patient to your knowledge?
A To my knowledge. It may be in

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Dr. Iakovlev's, but I don't know.
Q And you understand that doctors are the ones who actually do differential diagnoses and draw conclusions about what complications patients have?
A Could you explain differential diagnosis, please?
Q Let me ask you, do you know what a differential diagnosis is?
A Not precisely, I don't thinK. So I suppose I wouldn't do that. I mean, it sounds like a medical term to me.
Q Opinion number nine, explain that opinion to me. Clearly, this is different.
A So after reviewing all of the Ethicon documents and some published papers, my conclusion was that this TVT Abbrevo mesh is stiffer. There are several e-mails from inventors of the mesh, such as Dr. Della Valle, Dr. Nelson, that observed this increase in stiffness, complained about an increase in complications, asserted that this mesh was different, and you could not rely upon TVT machine-cut mesh data to support the notion that TVT Abbrevo is the same.

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I reviewed mechanical testing done by Ethicon, and an effort by Dr. Kammerer, I believe, who is a fellow at Ethicon, who basically replotted some of those data and argued from Lynn that the mesh is subject to the very small forces in this environment. And when you compare over that very small force range, he reported that the elongation, the mechanical properties are the same.

I do not think this is a good way to approach the problem. I think you would have to consider as in the paper by Dietz, where he went out to 80 percent, something -- okay. So with the original Ethicon testing, they went to 14 or 15-percent elongation. The Dietz paper went out to maybe 80-percent elongation. And at those higher elongations, there are significant differences, stiffness of TVT machine-cut and TVT laser-cut.

Dr. Kammerer only plotted the data over a range of up to about a 4-percent strain elongation, and that was just a very limited range. He concluded that they were similar, but I questioned the physiological relevance of his approach in asserting that Lynn could

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be used to support that assumption. That's my opinion.

So the mesh, I believe, is stiffer. And the decision was made to use the TVT machine-cut data that is for the laser-cut product even though it was different. That's my opinion on number nine.

Q So you looked at the e-mails where Dr. Della Valle or others may have written in comments about the mesh being stiffer, correct?

A I reviewed those e-mails, yeah.

Q So you read those the e-mails, and you basically took as what they said to be as true, right?

A I read as much as I could read. I read a lot of documents.

Q How about this, what independent testing did you do, if any, to confirm or not confirm the supposed higher level of stiffness of the mesh?

A Well, honestly I felt like I didn't need to do independent testing. This is Ethicon data that they relied on to make decisions. That's what I'm criticizing. I'm criticizing

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the decision-making process, not -- I did not test these meshes mechanically. I'm making this opinion on the basis of Ethicon documents where they chose -- they deliberately selected different ranges over which to view the mechanical data. That's what I'm questioning.

Q Well, I'm going to get to that. My focus is on the e-mails.

Basically, what you did is you looked at some e-mails that some people wrote, and you adopted what they said, correct?

A Well, what do you mean I adopted what they said?

Q Did you assume what was written on the paper was accurate or true?

MR. KUNTZ: I'm just going to object.

A I'm still not getting it. I mean, there was statements by these surgeons that said it's not the same.

BY MR. SNELL:

Q Okay. This is what I am just asking -- maybe I'm making it too complex.

A Okay. I'm just not getting something.

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Q You saw some statements in an e-mail?

A Yes.

Q And you read them and what they meant to you, right?

A Yeah. It seemed like a straight forward statement. And I read it and that's what it said, so I just --

Q You didn't apply any further analysis to this statement?

A What further analysis would I have applied? It is just what it said. There were multiple e-mails and there was an e-mail chain. I read the question, and I read the response, and I -- I mean, I did my best to review it, but some of these comments were rather blunt and direct, so it was --

Q So you interpreted the statements without doing any testing of their veracity or -- of the points?

A I don't know how to test their veracity. It just -- I mean, there were multiple statements and there were multiple e-mails that seemed to -- among Ethicon employees that addressed this as a concern, so it just wasn't one e-mail. It was -- there seemed to

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be many documents posing the question is TVT machine-cut the same as TVT laser-cut Abbrevo -- laser-cut versus the machine-cut.
There were numerous opinions and documents going back and forth. Many were questioning this decision. Others were promoting it. There was -- it looked like a fair amount of descension until Dr. Kammerer did his analysis, and then what appeared to me is that the decision was taken that these products are the same.
So I read a lot of documents to form this. I mean, if there is another one you would like me to read, I would be happy to read it. That's why I'm here. But this is what I read, and this is what I saw, and this is the opinion I came to.
Q I mean, these were basically e-mails written by other people who wrote into the company. And that's what you looked at, correct?
A Yes, but some were internally e-mails between -- conversations between Ethicon employees and Europe and North America and --
Q Fair enough.
These are people writing e-mails to other

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people, correct?
A Yes.
Q The laser-cut and the mechanical cut mesh, they are the same mesh, correct?
MR. KUNTZ: Objection.
A I would say they are cut from the same Prolene mesh, but I would not say that they are the same mesh. One has cut edges with a machine, the other has a cut with a laser. That's not the same to me. But if you want to say they're prepared from the same source mesh, I believe that's correct.
BY MR. SNELL:
Q Both of the meshes are made of the same Prolene polypropylene, correct?
A That's my understanding.
Q And it's the same mesh that goes through all of the same extrusion and manufacturing processes up until the point when it's cut to your understanding, correct?
A That's my understanding.
Q Right.
The only difference is the edges of the strip of tape, one is cut mechanically and one is cut with a laser, correct?

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A That's the difference -- to my understanding, that's the only difference in how they are manufactured, but that could introduce differences -- well, okay.
Q But they are the same in that respect, correct?
A The same in what respect?
Q That they are the same up until the point when they decide to cut the edges of the mesh either mechanically or they do it with laser, correct?
A I understand, yeah.
Q Is that correct?
A I believe so. I mean, I don't have the details of how these are --
Q So if we have two pieces of mesh, this is mechanical, this is laser, is there any difference in the mesh that is running down the middle?
A I don't know. That has not been tested. All I can say is that they are cut differently. What affect that has on the mesh in the middle, I don't know that that's been tested.
Q They are knitted the same, right?
A Yeah, but that cutting operation could change

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something. I just don't know and it's not been looked at.
Q Well, Dr. Kammerer looked at it, right?
A No. Dr. Kammerer, I don't believe he actually did any testing. I believe Dr. Kammerer took data from previous experiments and replotted them over a different range of elongation. That's what I believe he did from the documents I saw.
I didn't see -- all I saw in his report was that he noted that he was using data from other reports. I didn't see like he actually did do measurements. That was my understanding.
Q The elongation of the mesh, the mechanically-cut and the laser-cut, were the same at out to I believe it was 5 percent. Do you have the document?
A It would help if we had the document. I was going on my memory. I believe it was 4 percent maybe. It was not very many. I believe it was 4 percent. It would help if we had it. I don't know if it's on the disk or, I mean, how easy it would be to find.
Q It will be on there. I'm sure if you'd look

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at it, it's on there.
MR. KUNTZ: What are you looking for again?
MR. SNELL: Kammerer's paper, the elongation testing.
MR. KUNTZ: Which one?
MR. SNELL: The analysis he did on elongation of the laser-cut versus the mechanical-cut. I want him to be able to look at it.
(Off-the-record discussion.)
BY MR. SNELL:
Q Have you ever tested the forces in the pelvis?
A No, I have not.
Q What is your basis for saying that the reliance on the Lynn period paper is wrong?
A Okay. So there is another -- okay. There is another e-mail by Dr. Kammerer, where he comments that the elongation on the mesh could be as high as 50 percent when it is implanted. And, obviously, if the mesh is elongated when it's implanted, that's going to move you down the force-distance curve.
And the other point about Lynn is that

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what Lynn was really measuring was a differential force. So Lynn was measuring -- so the patients were grafted with this what looked like the autograft fascia sling, and he was measuring the force when they cough with a full or empty bladder. That is a differential force. You don't know what the initial force or tension of the elongation of that sling was.
And the differential forces that he was measuring were so small. They are something in the range of .1 to .2 pounds. I mean, that's like taking the meat patty from a junior cheeseburger and hanging it on -- I mean, we are talking forces that are really small. And that's a differential force on a sling when somebody coughs.
It just doesn't seem very plausible to me. It's a very small force. If the sling is elongated up to 50 percent, when it's -- then it's got some strain, and you don't know what that is. But that's going to make the stiffness higher if you're moving down that force-stiffness curve. That's what I'm saying.

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Does that make sense?
Q This is the sling under the urethra, correct
A Yeah.
Q Do you know the size of the urethra?
A Probably pretty small.
Q So that low number, that small number -- do you understand that? Do you know whether that is consistent or inconsistent with basic anatomy and physiology of the urethra, in the support structures lying underneath the urethra?
A It just seems to me that the sling in that study is different from the slings that are being used as the TVT. It's placed differently. I just don't know that you can make that same extrapolation, that the force on that autograft sling when somebody coughs is the same. It just seems --
Q Do you know that you can't? I mean, have you done any testing or done any research that ever shows that one cannot do that?
MR. KUNTZ: Objection. From what he has already said? From what Kammerer has already said? I just want to make sure we're clear.

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MR. SNELL: No, I'm asking him. He says he doesn't know. Well, what I'm asking you is --
MR. KUNTZ: He just referred to Ethicon's own document, where Gene Kammerer said it was different. Besides that?
MR. SNELL: No, he didn't.
MR. KUNTZ: Yeah, he did. He said his e-mail -- yes, he said exactly that. And now you're trying to say that he didn't.
A I'm saying that Dr. Kammerer said that when you implant a sling, it can elongate as much as 50 percent. And 4 percent -- I mean, I've seen these slings. For 4 percent, that's like -- 4-percent elongation is like folding it out of the box. I mean, it's such a small amount.
When you install it, it could be 40 or 50-percent strain, and that moves you much further down that stress-strain curve where these materials become very, very different. That is Dr. Kammerer's email. And then he takes this paper from Dr. Lynn that says, well, actually, the differential -- he doesn't even call it a differential force, so

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that's what it was, because he doesn't know the initial force on that sling.
He just knows that when somebody coughs and exerts an additional force, that force was in the range of half a newton.
BY MR. SNELL:
Q How do you know what Dr. Kammerer knows?
A Well, that's what he wrote.
Q Well, you just testified that he didn't know something. How do you know that?
A What did I say? I don't know what I said he didn't know. I don't know. He said that when you implant the sling, it can extend, it can elongate as much as 50 percent. Well, that's a lot more than 4 percent.
Q Do you know what that was in the context of and what type of testing that was in the context of?
A In my understanding of reading that e-mail, that was in the context of the procedure, of implanting the sling.
Q The 50-percent elongation testing you've seen done, they didn't even have the sheath on the mesh; is that correct? Do you know what I'm talking about? Have you seen 50-percent

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elongation testing?
A I'm not talking about testing. In Dr. Kammerer's e-mail, he talked about with the meshes and the procedures he's observed, the mesh can elongate up to 50 percent. That was, I think, the language that he used. So that tells me when it is being implanted, it's elongating. It's no longer -- it's not 4 percent. I mean, he is saying it could be up to 50 percent. That is a much bigger number than meaning 4. So I'm questioning how he got this -- he basically took this number of 4-percent strain, which is very low, so he could argue that -- that's what it looks like, that he could argue that over that very small strain that these meshes are, in fact, the same.
Q That is your inference of what was going through his head?
A That's what he said in this document. He puts that number for Lynn out, and then he goes to that stress strain curve, and he plotted the data over that range that he felt was physiologically relevant on the basis of the findings from Lynn. That's what he did.

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That's what he says in the report.
I mean, I can read from it if you want to, but that's to me what he said. He used Lynn to justify that half a newton of force.
Q Have you have read Dr. Kammerer's deposition?
A I can't remember. I don't know. I don't remember anything specific from his deposition.
Well, I would be interested to --
Q You would be interested to what?
A No, I'm just --
MR. KUNTZ: I would be interested why we got that e-mail after his depo, but we can take that up with somebody else.
BY MR. SNELL:
Q Item number ten, I think this was something that was in Huskey, but you tell me if I'm wrong.
A There is an element to that. What's new here would be referring to this laser-cut versus machine-cut. I don't believe -- to my knowledge, the studies that were done were this mechanical testing that I was referring to. There was a 14-day rabbit study where

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they were measuring the infiltration, and they were measuring pull-out strength, but it was a very short time point, only 14 days.
And then there were e-mails from some of these clinicians saying that we can't -- you just can't use TVT machine-cut clinical data to support TVT machine-cut, the notion that the TVT laser-cut would perform the same, because the meshes are different. And I don't think they did enough testing to establish whether they were different or not. I would have liked to have seen more testing to establish that fact.
Q What testing was done?
A What testing was done?
Q That's you're aware of.
Well, let me back up.
A Okay.
Q Did you do a PubMed or any other kind of search to see what clinical literature there was on the Abbrevo or laser-cut and mechanical-cut meshes?
A I think there is some study on TVTS, which is a -- but that product is off the market now. I was relying heavily on these Ethicon

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documents, what they did, and the conclusions that they drew from the testing that they did. And I just thought that it wasn't -- it wasn't enough. It wasn't convincing from the way that the whole Kammerer conclusions were drawn to a 14-day rabbit test. There should have been more preclinical testing.

I mean, why did they not file a new 510(k)? That could have been a relatively straight forward thing to do.

But to my knowledge, they didn't even file a new 510(k) for the laser-cut mesh. They just said it's the same without really enough testing to reach that conclusion. There was a process change that was just made and never really validated. That's what that opinion was saying.

Q The e-mails from the clinicians, that's the same ones we talked with about with regard to opinion number nine?

A Yeah.

Q And the 14-day rabbit study?

A That's what I remember. I think there was a 14-day rabbit study.

Q Do you know if that is the type of study that

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is normally done in the industry to assess pull-out force?

A That was my understanding.

Q Have you have ever conducted that type of study?

A I have not. And I think that answers one question about pull-out force, but I don't know that that addresses his question of differences in stiffness between the mesh. And then these clinicians are saying that they are seeing more complications. So there were clinical warnings coming back that this -- that something seems different here.

Q Are you a regulatory expert, such that you can cite to any regulations right now that say that Ethicon should have filed a 510(k) specific to laser-cut mesh?

A I'm not -- I have a working knowledge of FDA approaches.

Q If you're going to offer an opinion about a 510(k) --

A Let me think about it for a minute. I know where you are going with this. I just -- Let's see if we can work through this.

Q Well, my question is, are you going to try to

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offer an opinion that a 510(k) should have been filed for laser-cut? Because if you are, I want you to tell me --

A I know what you want me to tell you.

Q -- the regulations, and I want you to tell me exactly what documents they should have looked at. I want you to basically sit there and be a regulatory expert.

A I get it.

MR. KUNTZ: He will not be giving that opinion.

BY MR. SNELL:

Q Can you just tell me you're not going to give that opinion and then I can move on?

A I'm upset about what was done. But so we can move on, I'm not going to give that opinion as a regulatory expert. There were just things that concerned me, but I'm not going -- okay. I will retract that.

MR. SNELL: Jeff, he is not going to get up at trial --

MR. KUNTZ: He's not going to give a 510(k).

A I'm not giving a 510(k) opinion.

MR. KUNTZ: That's what you want

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to know.

A I'm not giving a 510k opinion.

BY MR. SNELL:

Q Because that's a whole other issue.

A I know.

Q There is nothing in your disclosures that say he is a regulatory expert and he's talking 510(k)'s.

A I just have enough knowledge of this that I saw things that disturbed me, but I'm not going to give that opinion as a 510(k) expert. I will stick to what I told you. I will reign myself in. You are provoking me a little bit. I'm not frustrated. I'm just --

Q You know what they say, some knowledge is dangerous.

A I'm going to stay within the scope of my opinions that are written here.

Q Thank you. I would like that.

Okay. Are there specific scientific studies that Ethicon should have done that you are going to say would have produced some type of clinically or statistically significant difference as between the meshes?

A I would have liked to see a longer term

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implantation test than just 14 days. I think if there were differences in stiffness, you might have seen it in 90 days, but even longer periods would have been -- this mesh could have been tested in preclinical models more relevant to the vaginal wall. So there is something new in my reliance materials.

There is an abstract by Deprest, D-E-P-R-E-S-T. That was published in 2013. It's in the reliance materials, where they had a large animal model where they compared mesh in the abdominal wall to mesh in the vaginal wall, and they saw eightfold more contraction in the vaginal wall.

So I think these studies could have been done by Ethicon to assess these differences. I think they could have interpreted their own mechanical data more conservatively. We already discussed that, so I don't want to bring that up again, but those are the studies. But more preclinical studies and a more thoughtful evaluation of their own mechanical data is what I would say.

Q You're not saying that Gene Kammerer, who has got 40 years of experience, is incompetent,

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you just disagree with -- let me just finish. You're not saying he is incompetent, you just disagree with what he did?

A He might be too confident. What he did was -- I don't like it. I don't like the way that he handled the mechanical data to say that everything was the same. I think that was a flawed approach. I'm not saying he is incompetent. I don't like the way he approached that problem. I shouldn't say don't like. I disagree with it.

Q But you have not conducted any independent testing or analyses that would show what he did was incorrect?

A I have not done any other testing. I was relying on Ethicon documents at the time of testing.

Q This Deprest 2013 paper, what type of animal model was that? Was that a pig?

A It was a sheep. It is an abstract, I believe, in the IUGA meeting in 2013. It's in the reliance materials. That's new.

Q Do you know whether the laser-cut mesh has ever been subjected to testing in a sheep?

A I don't know if there was testing in that

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model. I don't know.

Q Would it surprise you to learn that laser-cut mesh has been tested in sheep?

A In what model?

Q The sheep model.

A You mean on a wall model? On a subcu model? Where in the sheep was it tested?

Q I guess my question is, would it surprise you if you learned that it was done?

A Would it surprise me? I know that there was a lot of testing done. I wasn't aware of the study that tested in the vaginal wall. If it's a subcu test, then, again, that's a different environment. The interesting aspect of the Deprest study to me was that they looked at differences -- which they asked the question, is it different in the abdominal wall versus the vaginal wall.

And I haven't seen a document that -- I mean, I would be happy to look at it if you've got one, but I haven't seen that.

Q This study by Deprest, how big of a size of a mesh was implanted? Do you know?

A I can't remember the details from that. It's in the abstract. I don't know.

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Q Do you know how they implanted it in the vaginal wall?

A I can't remember how they did that.

Q It wasn't a sling put between the vagina and the urethra?

A I don't believe it was a sling. I believe it was more -- I just would have to look at it again to remember it, but I don't believe it was a sling. I think they implanted the piece of mesh, but I can't remember the details of how they did that.

Q Do you know when was a sheep model where implantation in the sheep's vagina was first perfected?

A I really don't understand. You mean as a sling or you mean as like an implant? I'm not sure what you mean.

Q As a model. Usually animal models, right, you just don't come up with some theory and do the model. Don't you have to test models before you actually do them?

A Yeah. I mean, I work with colleagues where we design new models for bone healing.

Q Is there a way to validate models? I guess that's what -- I'm kind of getting towards,

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that area.
A Yes. So if you want to validate a functional model, that's a different question. I think what they did in this study is they just implanted it adjacent to the tissue. I don't think it was intended to be a functional sling model.
They were just asking the question, well, if I implant it here at the hernia abdominal wall versus here in the vaginal wall, do I see differences in cellular infiltration and contraction and those kinds -- it wasn't a -- this abdominal wall model has been around for a while, right. So I think what they did that was different is they implanted it in the vaginal wall as well.
Q It wasn't validated, though, as between the vaginal wall of the sheep and the abdominal wall of the sheep?
A I don't know what you mean by validated. When I think of validation, that's like a functional model that you have to validate to make, so if you wanted to make a sheep sling model, you would have to validate that. I understand that, but I don't think that that

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is what they did.
Q This wasn't a validated sheep model study?
A I would say it wasn't a validated sling model. They weren't modeling the sling in the sheep and trying to draw some conclusion about how the sling would act in a human. I think they were just asking a question, how would this mesh infiltrate in these two different environments. That's what that model was, which I think is a legitimate thing to do.
People have been implanting -- there is a number of rat abdominal wall models in other rodents and large animals. I don't think that is a -- I think that is a good approach.
Q Have you ever seen it done before, implantation of mesh in a sheep or a large animal's vagina?
A That's the first I have seen it, but there may be other studies.
Q Did you do any investigation to see whether the findings were consistent or inconsistent with other testing or whether anyone had tried to do that before?
A I have looked for other studies and that's

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what I've found. I haven't -- well, I have looked. That's what I know right now.
Q So have we discussed ten?
A I don't have anything to add to ten.
Q And 11 is similar to number ten -- or how is that different from anything you talked about in Huskey?
A Let me read it for a minute.
Q Sure.
A I think the point in 11 is that when I say did not consider -- I think there is a lot of overlap with Huskey. They do not consider principles of biomaterial science by not testing it in an oxidative environment using a known test that was known since the early 90's. Even though they knew and from their own studies, they saw evidence of oxidation and degradation, they never tested it.
So to me, biomaterial science, if I know something is susceptible to oxidation, I need to test that and assess it. And I guess what would be new here is that, you know, we have tested that. In one exemplar of TVT mesh, we found that it can't oxidize. And that test could have been done by Ethicon. That is

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what I'm saying in 11 that is new.
Q You're saying that test could have been done by Ethicon?
A Yes.
Q But somebody at Ethicon would actually have to believe that this cobalt study that you referenced and the solutions are what actually occurs from macrophages at an unknown concentration in the body, correct?
MR. KUNTZ: Objection.
A Yes. And there is some well-trained scientists at Ethicon. Those papers have been cited dozens of times and are well established in the field. They are well known in the field. Those papers were instrumental in discovering the problem of the instability of polyether urethane catheter leads, that these leads would oxidize, degrade, and in some cases fail. Those products were withdrawn from the market.
So if I were at Ethicon, and I knew that story, I would be very worried about this, because it's the same type of problem, a chemical attack. It's just an environmental

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stress cracking problem, where you have an oxidative environment and materials sensitive to oxidation and mechanical forces. All of those can lead to this environmental stress cracking in device failure.

So if I were at Ethicon and I knew of those problems with those urethane catheter leads, one of the first things I would have done is tested these meshes in this oxidative environment so I would know.

BY MR. SNELL:

Q The urethane catheters, were those Ethicon products?

A No. But a good biomaterials scientist recognizes that these are two polymers that are sensitive to oxidation. And I would at least want to know -- I would want to know, does it degrade, does it oxidize, does it degrade. I think you have to ask that question when you're designing a biomedical device, what's the material made of and is that a problem.

Q Well, there could be folks at Ethicon who have relevant experience who look at the paper by Anderson and this cobalt solution,

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and say that test doesn't actually look like it or is representative of the foreign body reaction in the body. I mean, couldn't scientists come to that conclusion?

A They could. But, again, this is a well-accepted test that's been cited a lot and used a lot. I think it should at least raise some questions, especially when you have your own studies showing evidence of oxidation. So it's not only the literature, but it's also these own suture studies, the dog study, Guidon study, that showed evidence of oxidation that should have sent off some red flags, hey, this material is sensitive to oxidation, why don't we test it. That is what I am saying.

MR. SNELL: Let's take a break here. We've been going for a while.

(A brief recess is taken from 4:30 to 4:40 p.m.)

BY MR. SNELL:

Q Doctor, I want to circle back around to your test, the testing that you were involved in.

I just want to make sure that based on that test, you're not going to come into

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trial and tell the Perry jury that based on the testing you did on that single TVT device that there could be degradation in the human body by a certain time point?

MR. KUNTZ: Objection.

A I've not testified and I don't plan -- I've been saying and I still say that it's unpredictable. There is no certain time point. It's unpredictable.

BY MR. SNELL:

Q Okay. I just want to make sure I understand how far you were going to try to take this study.

Just so we're crystal clear, you're not going to walk into that trial and say, at one year, you can see degradation from the TVT mesh, and I know it because of the study I did on the TVT device?

A No, I'm not saying that.

Q Okay. Did you do power calculations on your TVT device study?

A It's an in vitro test. We typically do power calculations on preclinical studies. But in the in vitro test, it's in vitro, where it's -- you know, it's --

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Q You need to do power calculations on the front end of this test if you're going to try to do statistical significant testing on the back end, isn't that correct?

A My experience with power calculations, again, is typically in an in vivo study where we estimate -- it's so that we ensure that our study is power enough. If we estimate a certain variance in a certain number is 10 percent, we want to be able to power our study to make sure that we can see that 10-percent effect.

But this is an in vitro study, so, well, we did the study, and either we will see a significant difference or we won't. That's what it is. If we don't see a significant difference, then maybe the study wasn't underpowered, but we report that it is if it's not significant. But it's either significant or it's not.

I mean, the reason you do a power study in a preclinical study is to make sure you have got enough animals to do your study. In an in vitro study, well, if we don't see significant differences in the in vitro

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study, then our conclusion would be that it's just not a significant difference.
Q Isn't it true, Doctor, that if you do not do power calculations on the front end of a study, you can't say that there are statistically significant findings on the back end, because you haven't even assessed whether you have an adequately powered study?
MR. KUNTZ: Objection.
A I don't think that's true in in vitro studies. I don't see people doing this. I don't see papers where people power their in vitro studies. We typically do enough replicates that we can calculate a standard deviation and run an ANOVA or a t-test or something, but we don't -- in a clinical trial and in an animal study, we do power analysis all the time, but I just -- I don't --
BY MR. SNELL:
Q Did you estimate the potential rate of error in your study before it was done?
A Potential rate of error in --
Q In finding discrepant findings?
A I just don't know where you are going with

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this.
Q Did you do it or didn't you do it? Did you do a calculation to assess the potential rate of error before you started that study on the TVT device?
A We didn't do that calculation.
Q Did you estimate the variance as you noted earlier?
A But this isn't the way statistics works. I mean, if we have two populations, we can compare by a t-test. We can compare those populations and draw within -- we assess P to be .05, and so with this value of P, we can say it's significant or not significant. That's typically what people do in in vitro studies. We say P is .05, and then we do this -- we can calculate a P value. You can do it either way.
But if you have two populations, you can compare those populations using statistical analyses. My experience with these power analyses is a lot of it comes down to an ethics concern. It's not ethical to do an animal study that is insufficiently powered.
Because if you do the study, and you

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can't see differences, you don't know -- it's part of justifying the numbers of animals that you're going to use in your test. But if you have two sets of data, you can compare whether they are statistically different or not. This is what people do. It's an in vitro test. I just don't know where you are coming from.
Q When you do studies, you want to have adequate sample sizes so that you can tell if the results are meaningful. That's a fair statement, right?
A Yes, but you can tell if the results are significantly different if you see a significant difference. You can calculate a P value. You can do a t-test. You can do an ANOVA on that date. If you don't see a significant difference, then one reason could be you didn't have enough replicates. But if you see a significant difference, I don't understand how it's not significant. If you see a significant difference between two groups, they're different. That means the differences are -- I don't understand. I mean, this is like statistics that you learn

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in school. I mean, comparing two populations.
Q Yeah, but here the two populations was a TVT device and a polypropylene pellet. It wasn't 100 TVT devices and 100 pellets, was it?
A You are so confused on statistics. I made this clear. We tested one exemplar, but we cut multiple pieces from each exemplar. So we have replicates. So we can say, statistically, in that mesh that we tested is there more oxidation from the FTIR spectra at week five compared to week four compared to these other weeks.
We can do that test through even just -- we could do a two-way ANOVA to compare changes in time and changes in the mesh or between groups and as a function of time. We can do that analysis and that can be -- that's what people do all the time.
Q You can't do that analysis as between the control, though, because you didn't run all of the same tests at the same time, correct?
A I don't remember the details of that. We ran the control went out to four weeks. We ran the TVT out to five, and I think we might

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have had one that went to six weeks, but we just didn't have enough sample to go out that far.

But we can do all of these statistical analysis, and I will bring it to trial, and you can come at me with whatever you want about statistics, but I just don't see where you are coming from with this. I mean, we can do a statistical test to see whether there is differences at least in the function of time. That's how we are going to assess whether it is induced is the amount of oxidation at week five significantly greater than what we see at weeks, four, three, two, one or zero.

Q That hasn't been done, though, to this point? Or you didn't bring that with you today, right?

A It hasn't been done. We're working on it.

Q The tensile string, is that anything that you tested in this test of the TVT versus the control?

MR. KUNTZ: Objection.

A We didn't measure tinsel strength. This takes a lot of material. And, again, it

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doesn't answer the question of whether it can be oxidized. Tensile strength is a bulk test. So because it is a bulk test, it's testing the whole material. You may or may not see -- the problem with doing a tensile strength test is --

MR. SNELL: Can I move to strike? I don't want to keep you here later than I have to. It was a yes or no really.

BY MR. SNELL:

Q Do you do tensile strength?

A No.

Q All right. Did you do any elongation testing in your --

A No.

Q I don't see it in your opinion, but I just want to confirm this. You're not going to be giving any testimony on what a suitable alternative device for the treatment of stress urinary incontinence was that was equally safe and effective as TVT Abbrevo; is that correct?

A I did not testify on that and I don't plan to.

Q Okay. Are you aware of any evidence that the

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piece of mesh in Mrs. Perry's body became unstable from a polymer standpoint?

A No, I'm not.

Q Are you aware of any evidence that the piece of mesh in Mrs. Perry became brittle?

A No, I'm not aware of that.

Q Are you aware of any evidence that the piece of mesh in Mrs. Perry degraded?

A No.

Q I didn't ask you at the beginning. Have you given testimony at all since the Huskey trial as an expert --

A I provided this listing.

Q -- against anybody? I think you're right.

MR. KUNTZ: He gave you an updated copy since the Huskey trial. I think you have it.

A I gave testimony in Boston Scientific since the Huskey trial.

MR. SNELL: I have it right here. I'm going to mark it.

(Deposition Exhibit No. 5 was marked for identification.)

BY MR. SNELL:

Q Doctor, I'm handing you Exhibit 5. Tell me

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what that is, please.

A This is a listing of cases in which I provided testimony in the last four years. And there are five cases listed here in 2013 and 2014.

MR. SNELL: I'd like to mark what I believe is your CV as the next exhibit.

(Deposition Exhibit No. 6 was marked for identification.)

BY MR. SNELL:

Q Doctor, I'm handing you Exhibit No. 6. If you would just identify that for the record.

A This is my CV. It lists all of my academic and professional experience.

Q That's current?

A Yes.

Q Okay. Earlier you talked about environmental stress cracking?

A Yes.

Q Is that something you need to look at on SEM to assess?

A I would assess environmental stress cracking by SEM. There are other methods as well, but SEM is one.

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Q What are the other methods?
A The microscopy methods with Dr. Iakovlev.
Q Are you aware of any evidence that the piece of mesh in Mrs. Perry has or had environmental stress cracking?
A I'm not aware of any evidence.
Q Earlier we talked about the concept of macrophages in foreign giant body cells being quiescent?
A Yes.
Q You are aware that those cells can be quiescent, correct?
A I'm aware that this is an active area of investigation. I'm aware that there is a lot of research activity trying to make these cells quiescent or inactivate them. I'm not aware of any reports that have definitely proven they're quiescent or what makes them quiescent. I would be happy to look at it.
I'm familiar with this idea, but I'm not familiar with any studies that have proven that or shown under what conditions that can occur.
Q You are aware actually that scientists are able to now incubate and generate quiescent

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tissue macrophages for use in studies? Don't you know that?
A Well, I would like to see the document you're referring to. I just said I haven't seen that. I am aware of this idea, but I haven't seen that study. I would be happy to look at it, but I --
Q My question is not pertaining to a specific study. It's do you know whether scientists have generated incubated quiescent tissue macrophages for use in studies?
A I'm not sure what you're referring to. I mean, I would have to see a study to -- I'm aware of this area of research, but I can't comment on it without talking about a specific study at least. What am I going to say? I don't know where --
Q Let me ask you this. You know that scientists manufacture different cell lines for use in studies, correct?
A There are different permanent cell lines that are used in cell culture. I use them in my own lab.
Q So somebody, scientists or companies make those, correct?

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A We can buy those from companies. There is an immortalized cell line that you can buy.
Q So my question to you, then, is, do you know whether there are available for purchase or use quiescent macrophage cells?
A I don't know. I've never purchased them, but that doesn't mean that they happen in the human body. Again, without seeing a document, it's difficult to comment on that.
Q How would one definitively prove that macrophages in giant cells become quiescent in the body?
A Well, I would challenge it with a foreign body, and different time points, harvest the cells, and stain for myeloperoxidase. But it's -- to assess that they are actually quiescent -- I mean, you have to count the number of cells, and then look at the amount of myeloperoxidase, look for degradation. It would be difficult to show that they are completely quiescent.
Q So what would you have to do to prove that those cells are activated every day of the year for ten years? You would have to do the same test, wouldn't you?

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A We talked about this earlier. What I know is Dr. Iakovlev, whenever we stain for myeloperoxidase, we see it. So does that conclusively prove that every cell is always -- Dr. Anderson's 2008 review says that these cells are activated and adherent, and this reaction doesn't stop. That's what he says.
Q How is that proof? What test has been done under the proper methodology that shows that those cells are always activated every day for a long period of time? Has anybody done such a test?
A Not that I know of. But why would they stop? Why would they --
Q Well, I understand that Dr. Anderson may believe that or he wrote something to that effect. But has that methodology been tested to show that they are always in an activated state day after day after day?
A All I can say is that in my experience with this is that they are activated. When I talked to Dr. Iakovlev, did you stain for myeloperoxidase, his response was, why would I stain for myeloperoxidase, it has to be there.

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Q Dr. Iakovlev assumes it's there. But he has not tested for myeloperoxidase on a continuous basis, daily or weekly basis in samples?
A I tell you what, I think most people will be convinced by it.
Q Can you answer that question, please? That is what Dr. Iakovlev believes, right?
A Yeah.
Q But has he tested for myeloperoxidase in the same samples longitudinally week after week after week after week to see that those are activated?
A Not to my knowledge.
Q All right. And you haven't done that type of testing, correct?
A No. But in my experience, when I see macrophages and stain for myeloperoxidase, I've not seen this type of stain. I need to qualify my comment. When I see this adherent macrophages in the foreign giant body cells in my work, they appear to be activated.
Q All right. You can see macrophages and they're not activated. That is well known, correct?

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A I don't know that I would say that that is well-known. I don't know under what conditions -- I mean, I would have to see a study.
Q Well, let me make it simple. Can macrophages be present and they're not activated?
A In theory, it's possible. I'm just going by my own experience. When I see these adherent macrophages, they're activated. They're secreting this myeloperoxidase. There is degradation. That is what I've seen. I will be happy to look at an example where that is not the case, but --
Q If there are chronic inflammatory cells present, that does not necessarily mean that they are active. Is that a fair statement?
A It's my opinion that they are active. I mean, I -- can I say that there is a study showing that they are always active all the time, no. But I believe they are active unless somebody shows they are not, and I would like to know under what conditions made them not active.
Q There is no test or study that shows that these inflammatory cells are always active?

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A You already asked this. I said I don't know of a study that showed that. I'm just going from my own experience.
Q Do you know if Dr. Iakovlev has done any type of longitudinal study of myeloperoxidase and what it should show when properly applied to samples from the same source over time?
A I mean, he's a pathologist. He looks at patient explants. You can't do a study like that in patients, so I don't believe that he has done that study.
Q Did you bring anything else that we haven't marked?
A I think that's it.
Q When you do statistical significance testing, do you try to generate confident symbols as well?
A Sometimes. It depends on what we're trying to do. Sometimes when we establish P at .05, sometimes we can calculate a P value. We've done several different things.
Q Have you actually personally ever calculated a Bonferroni correction for multiple comparison?
A When I was in graduate school. My students

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do those calculations now, and I review them. There are software programs that you can use to do this. It's pretty routine, I think.
Q The software plugs in the number of tests and the time points and it generates --
A We can do this with software, yeah.
Q You haven't published or presented on this test, correct, that was done with the TVT device and the pellet control?
A We presented it at the AICHE annual meeting. And I think those slides are on the reliance list.
Q For the TVT?
A In that presentation, we did not identify the source of the mesh.
MR. KUNTZ: I don't think that's on there, Burt. We will get it to you, though.
A We called it mesh 1, 2 and 3. We did not identify it as TVT.
BY MR. SNELL:
Q Do you know if it was TVT or would you have to go back and look?
A Yes, it was TVT. We chose not to disclose that at that meeting.

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Q Where was this at?
A The AICHE, it's the American Institute of Chemical Engineers. If you would like, I can circle it on my CV. Would that help you?
Q Sure. That's fine. Or if you just want to look at your CV and tell me what page or number.
A That's fine too. On the CV, it's presentation number 154.
Q Was that a presentation that you actually gave and presented or did someone else do it?
A Dr. Dunn and I both gave the presentation.
Q Was it presented orally?
A It was.
Q Okay. So I would like to request a copy of that.
Did you have to prepare a manuscript in connection with that?
A No. We submitted a short abstract, which is available online. We elected not to submit an extended abstract.
Q What was the reason why you didn't submit an extended abstract?
A We typically don't do that for that meeting.
Q Is that the only presentation you have made

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concerning the TVT mesh?
A Yes.
Q Have you made any other presentations that concern transvaginal mesh?
A That's the only one.
Q On opinion number one, you say chemical degradation, embrittlement, structural degradation and other changes.
A Yes.
Q Are there any other changes that you're referencing that you're going to be talking about at trial in the Perry case? That just seems kind of broad based, and I want to make sure I understand where you're coming from with what other changes means.
A I would probably say I think structural degradation, embrittlement, and chemical degradation are the primary ones that come to mind that I've testified about.
Q Okay. And number two where it seems to -- are you going to try to opine that certain complications occur in patients like chronic inflammation, pain and dyspareunia because of the mesh?
A I'm saying that changes in the mesh can lead

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to problems such as pain, erosion. The basis for this opinion is the Clave, Costello, Wood papers where they show changes in the mesh, and then how that resulted in degradation. And these are all complications, so these are meshes that failed.
And my opinion is that these changes in the mesh contributed to those complications like pain and erosion. Brittle plastic can cause pain. Embrittlement can cause stress shielding between the host tissue and the implant, which can lead to poor integration, erosions, and things like that. These are all points that I made previously in Huskey.
Q In Huskey, though, you didn't testify about that at trial as I recall it because you're not a medical doctor. Is that consistent with your recollection?
MR. KUNTZ: Objection. Go ahead.
A I think the Judge may have limited what I would have liked to have said, but I believe it's in the deposition. I don't think there is any change in what I'm saying, in what I've been saying in these depositions.

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Q And just so I'm clear, you didn't conduct any type of differential diagnosis to assess the cause of dyspareunia or pain or the potential causes, correct?
A No.
Q You didn't rule out any other cause or potential causes?
A I didn't rule out any other causes.
Q And you didn't investigate the rates of dyspareunia or pain in the general background and compare them to these cohorts?
A I did not.
Q And in Clave, it's fair to state that one cannot say that the complications did not occur before the degradation; is that right?
A It's not clear from Clave the timing of those events. My opinion is that these changes in the mesh led to those events. The mesh changed and there was an adverse event.
Q And the adverse events are also you mention on items number eight and nine, extrusions, inflammation, pain, and you mention erosions on nine, correct?
A Yes.
Q You didn't not do any differential diagnoses

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on those, correct?
A No.
Q You didn't assess causation by ruling in or ruling out different causes, correct?
A No, I didn't do that.
Q In the testing that Dr. Kammerer did we talked about earlier, where in the first 5 percent of elongation of the mesh, the mechanical-cut and the laser-cut were similar, do you dispute that finding?
A I don't dispute the finding that of the very low elongation. They are similar but --
Q Okay. That's my question.
A Yeah. Okay.
Q Did you look at the clinical expert report that was done by two medical doctors at Ethicon with regard to the laser-cut mesh and elongation?
A I think I reviewed that document, but I can't remember what it said right now.
Q Did that document affect your opinions?
A I would have to look at it again to see what it says. I don't remember.
Q Did you consider whether either of those doctors had any experience implanting slings

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in women?
A I would have to look at the document. I just don't remember the documents to answer these questions. I'd have to look at it.
Q Have you ever consulted with a urogynecologist or a urologist who has experience implanting mesh slings to discuss with them or learn from them the forces that are in play during implantation?
A No, I have not done that. I relied on the Ethicon documents.
Q The e-mails you were talking about?
A And the other documents, the reports, the papers.
Q Do you even know Dr. Dmochowski here at Vanderbilt?
A I don't know him.
Q Do you know that Dr. Dmochowski uses polypropylene mesh slings?
A That's my understanding.
Q Have you ever written or said anything to any of the doctors here at Vanderbilt to apprise them of what your opinions are?
A I have. I have contacted -- there is a urogynecologist in the group there, and she e

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suggested I talk to Dmochowski, but I understand he might have been a defense witness, so I haven't done that. I don't think I'm supposed to do that. So I have reached out to them, but it hasn't moved forward.
Q Has Dr. Dmochowski been an expert in any of the other cases you're involved in?
A I don't know for sure. I don't know if he is an expert or not, because I have to resolve this before I can contact him. But I have reached out to that group at Vanderbilt.
MR. KUNTZ: I wonder if he has disclosed his stuff to Vanderbilt.
(Deposition Exhibit No. 7 was marked for identification.)
BY MR. SNELL:
Q I am handing you Exhibit 7 from Vanderbilt. Do you recognize this to be from the Vanderbilt Health Website?
A This appears to be urogynecology in the way it's printed. I think that's what it is.
MR. KUNTZ: I'm going to object. This is not a complete printout. Are you going to show him the part two where they

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talk about all the mesh complication that they treat? Are we going to get the full document or just part of it?
MR. SNELL: You can do whatever you want. This is Page 3 of 3.
MR. KUNTZ: Well, I'm going to object to an incomplete document. It's a printout of part of the website.
BY MR. SNELL:
Q At the top it says, surgical treatments for stress urinary incontinence, including mid urethral slings. Do you see that?
A Yes, I'm aware of this. I've seen it.
Q Well, I guess my question to you is is this a website that you visited on the Vanderbilt website?
A I believe I did, because I had to find who to contact, but I believe they also do a number of revisions.
MR. SNELL: Move to strike.
THE WITNESS: Well, you asked. I'm sorry.
BY MR. SNELL:
Q My question was straight forward.
A They always are.

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Q They really are, sir.
MR. KUNTZ: Hold on. I'm going to object. You are showing him one document, and I just made my objection. It is not a straight forward question when you're not showing him the whole website. And he just said where is the website that shows all of the complications they're treating for mesh. So that is not a straight forward question.
MR. SNELL: That's not even a proper objection. That's not a proper objection in California. That's beyond a speaking objection.
MR. KUNTZ: You just said all of my questions are straight forward. And this is very much a trick question and not a straight forward question. So don't make your comments unless you --
MR. SNELL: Let's try it again and knock off the ridiculous speaking objections.
MR. KUNTZ: Show him the whole website.
MR. SNELL: Give the man a computer. You can have him look at anything.

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MR. KUNTZ: You bring documents and ask him questions. My job is to show up with --
MR. SNELL: You are wasting my time. You're giving speaking objections that are absolutely improper in California.
MR. KUNTZ: You are asking trick questions, and that's what he told you.
MR. SNELL: It's not a trick question.
BY MR. SNELL:
Q Doctor, I read to you surgical treatments for stress urinary incontinence include mid urethral slings. Did you see that?
A Yeah, I've seen it.
Q My question was, have you seen this part of the website?
A I believe so, but it's a printout. It doesn't really look the same. I have been on that website.
Q Under what circumstance, would you have gone to the website?
A I was reaching out to that group to discuss mesh. I have contacted an OB in that group. I can't remember the name right now, but I

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stopped because it's not proper for me to -- I don't know whether he is a defense witness or not, so I would have to resolve this before I would really do anything.
Q You did speak to a female urogynecologist?
A Yes. I can't remember her name.
Q Or do you know if she was a urologist?
A I can't remember. She was in this group. She has experience with mesh revisions. And one of my students, one of my medical students, did a rotation with her, and I contacted her, I think, in September, but I dropped it because of this concern about litigation.
Q Okay. Do you have any understanding of the antioxidants that are in the mesh for the TVT Abbrevo?
A To my knowledge, they are the same as they are in proline resin that I talked about at trial.
Q Okay. One of the opinions you gave in Huskey was less mesh is better; is that correct?
A That's correct.
Q Why don't you give that opinion here?
A Why don't I give that opinion?

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Q Why aren't you giving that opinion here?
A I don't think that was specified as an opinion. I don't recall that. I thought it was in the body of the report. I don't remember that being spelled out as a specific opinion.
Q Do you know Abbrevo uses less mesh that TVT-O, don't you?
A What do you mean by uses less mesh? The area is smaller, but what about the --
Q Well, answer my question.
A I'm trying to clear up the way you're asking it. I asking you, do you mean as it has a different density or it's a less area? That's what I'm asking.
Q Does TVT Abbrevo have less mesh than the TVT obturator?
A I mean, it has less surface area of mesh, but I believe the density of that mesh is still the same.
Q When you say less surface area, you mean it's not as long as the TVT-O, correct?
A Yes, I think that's what I mean.
Q It's still 1.1 sonometers wide approximately; is that correct?

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A To my knowledge, and I believe the density is the same as well.
Q When you say density, what do you mean by that?
A Grams per square meter.
Q Okay. But we can agree there is less mesh with TVT Abbrevo than TVT-O?
A There is less mesh -- the way you say it, I guess it's true.
Q Now, do you have an opinion as to whether TVT Abbrevo is the better or a safer device than the TVT-O?
MR. KUNTZ: Objection.
A No. I'm not comparing it to TVT-O.
MR. SNELL: I think I'm about done. Let me look back through and see if there is anything else.
(A brief recess is taken from 5:30 to 5:40 p.m.)
BY MR. SNELL:
Q Just a few more questions, Doctor. So I'm going to request that whatever the materials that weren't provided on the testing that was done be provided. I'm going to leave the deposition open.

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Is there anything you believe is important to your analysis --
MR. KUNTZ: Hold on. We're not leaving the deposition open.
MR. SNELL: You can say what you want to say. I'm leaving it open. I don't have all of the documents.
MR. KUNTZ: California law is you can argue --
MR. SNELL: I'm not going to argue with you. I'm either right or wrong.
MR. KUNTZ: Okay.
MR. SNELL: I'm either right or wrong.
BY MR. SNELL:
Q Is there anything you believe is important in your opinions and analyses that we have not discussed today?
A I believe we have discussed everything that is important.
Q Now, is there any work that you are planning on doing with this case after today?
A No.
Q Besides the statistical calculations?
A No. No testing is planned, just analyzing

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what we have, and preparing for trial, those types of activities.
Q All right. Is there a list of analyses that you can tell me or tell the court reporter that you plan to do?
A Plan to do testing.
Q With the testing or pertaining to this case?
A It's the statistical analysis and writing the paper. That's it.
Q What will you do if you do the statistical calculations and they turn out to not be statistically significant?
A Report it as not significant, like we always do.
Q What else?
A What do you mean what else?
Q What will you do to try to understand why they were not statistically significant?
A I don't know. I would have to think about that at the time it -- I don't think that that is what is going to happen. The peak is ten times bigger, and the aragores (phonetic) aren't that -- I believe it's going to be significant, and if it's not, then I will figure out what to do when that happens. I'm

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not going to misrepresent data.
MR. SNELL: That's fine. I'm going to leave the door open. I know counsel has a question or two.
MR. ROSEN: I've got one question.
CROSS-EXAMINATION
BY MR. ROSEN:
Q Good evening, Mr. Guelcher. My name is Dr. Rosen. I'm with Boyce Schaeffer Mainieri. We represent Dr. Luu. I just have one question.
Do you intend to offer any opinions regarding Dr. Luu at trial in this matter?
A I do not. My testimony is about the mesh and how it changes after implantation.
MR. ROSEN: That's all. Thank you.
MR. KUNTZ: Dr. Guelcher, I have a few questions for you.
CROSS-EXAMINATION
BY MR. KUNTZ:
Q With respect to the studies you've talked about, and the testing you did with Dr. Dunn, in the SEM, FTIR, and XPS, those are all

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studies or documents or data that you can review independently of Dr. Dunn, correct?
A Yes, that's correct.
MR. SNELL: Objection. You've got to give me a chance to object. Leading, compound. Go ahead.
BY MR. KUNTZ:
Q You repeatedly in your practice are going to have expertise reviewing those types of studies, SEM, FTIR, and XPS?
MR. SNELL: Objection. Leading compound. Go ahead.
A Yes, I do.
Q And if Ethicon did those studies or had those types of documents, you could review those independently, correct?
MR. SNELL: Same objections.
A Yes, I could.
Q The last question I have. Is there any peer-reviewed article that you're aware of that shows or supports the notion that macrophages in foreign body giant cells can be deactivated?
A I'm not aware of such an article.
MR. KUNTZ: Okay. No more

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questions.
REDIRECT EXAMINATION
BY MR. SNELL:
Q Are you aware of any book chapters, any articles in the peer-reviewed literature that says that macrophages can indeed be deactivated?
A I'm not aware of those articles. That's what I said earlier.
Q But you have seen it in the literature or in books that macrophages can be quiescent?
A That's not what I said. I'm familiar with this idea of reprogramming macrophages, but I am not familiar with any studies that have shown that this has been done or under what conditions it happens. I mean, I'm familiar with the idea. I'm just not familiar with such a study is what I'm saying.
Q You're not familiar with such a study that shows that macrophages are activated longitudinally every day for years and years?
A No one has proven that, but Anderson teaches they're activated when they adhere. That's what it says.
MR. SNELL: Move to strike part

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of the response, part of the answer.
I'm done. Thank you.
(Deposition was adjourned at 5:50 p.m.)
* * *

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STATE OF KENTUCKY)
)
COUNTY OF DAVIESS)

I, MICHELLE E. KERR, A NOTARY PUBLIC AT LARGE IN AND FOR THE COMMONWEALTH OF KENTUCKY, DO HEREBY CERTIFY:
THAT SAID DEPOSITION WAS TAKEN STENOGRAPHICALLY AND ELECTRONICALLY BY ME AND THAT THE TYPEWRITTEN TRANSCRIPT ABOVE IS A TRUE RECORD OF THE TESTIMONY GIVEN; THAT I ALSO RECORDED AND TRANSCRIBED ANY AND ALL OBJECTIONS MADE BY COUNSEL AND THE REASONS THEREFORE; AND THAT I AM NOT A RELATIVE OR EMPLOYEE OR ATTORNEY OR COUNSEL OF ANY OF THE PARTIES, NOR A RELATIVE OR EMPLOYEE OF SUCH ATTORNEY OR COUNSEL, NOR AM I FINANCIALLY INTERESTED IN THIS ACTION.

IN WITNESS WHEREOF, I HAVE HEREUNTO SET MY HAND AND AFFIXED MY NOTARIAL SEAL ON THIS _____ DAY OF DECEMBER, 2014.

_____
MICHELLE E. KERR, NOTARY PUBLIC

My Commission Expires:
March 21, 2017
March 21, 2017

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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SCOTT A. GUELCHER, PH.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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